UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

THERESA PITMAN, Individually and on Behalf of All Others Similarly Situated, Plaintiff, vs. IMMUNOVANT, INC. f/k/a HEALTH SCIENCES ACQUISITIONS CORPORATION, RODERICK WONG, PETER SALZMANN, PAMELA YANCHIK CONNEALY, FRANK M. TORTI, ANDREW FROMKIN, DOUGLAS HUGHES, GEORGE MIGAUSKY, ATUL PANDE, ERIC VENKER, SVB LEERINK LLC, LIFESCI CAPITAL LLC, CHARDAN CAPITAL MARKETS LLC, GUGGENHEIM SECURITIES, LLC, ROBERT W. BAIRD & CO. INCORPORATED, and ROIVANT SCIENCES LTD., Defendants.	Civil Action No. 1:21-cv-00918-KAM-VMS CLASS ACTION **AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** DEMAND FOR JURY TRIAL

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Lead Plaintiff SEPTA Pension Plan Master Trust ("Plaintiff" or "SEPTA"), by its undersigned attorneys, on behalf of itself and the class it seeks to represent, for its Amended Complaint for Violations of the Federal Securities Laws (the "Complaint"), alleges the following upon knowledge as to its own acts, and upon the investigation conducted by Plaintiff's counsel as detailed below.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of all purchasers, other than Defendants (defined below), of the securities of Immunovant, Inc. f/k/a Health Sciences Acquisitions Corporation ("HSAC," "Immunovant," or the "Company"), in or traceable to the Company's follow-on public offering on or about September 2, 2020 (the "September 2020 Offering"), as well as purchasers of the Company's securities between October 2, 2019 and February 1, 2021, inclusive (the "Class Period"), under Sections 11, 12(a)(2) and 15 of the Securities Act of 1933 ("Securities Act") and Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act"), as amended by the Private Securities Litigation Reform Act of 1995 ("PSLRA") and Rule 10b-5 promulgated thereunder (17 C.F.R. §240.10b-5).

2. Immunovant is a clinical-stage biopharmaceutical company developing a drug to treat several types of autoimmune diseases. This drug, referred to during the Class Period as IMVT-1401, was Immunovant's only product. Since IMVT-1401 was in the clinical trial stage during the Class Period, Immunovant did not generate any sales or profits from IMVT-1401. Immunovant's operations focused exclusively on overseeing and managing the clinical trial process for IMVT-1401 and attempting to show viability and secure eventual approval by the Food and Drug Administration ("FDA"). Before the start of the Class Period, Immunovant was a private company ("Legacy Immunovant") and a division of Defendant Roivant (defined below). Immunovant became a public company when it was acquired by a special purpose acquisition company ("SPAC"), commonly

known as a blank check company, in a deal valued at more than $400 million. Defendant Roderick Wong, who was the chief executive officer of that SPAC, owned approximately 3% of Legacy Immunovant at the time of its sale to the SPAC.

3. During the Class Period, Defendants praised the widespread benefits of IMVT-1401, described it as a "best-in-class" drug that was "safe" and "well-tolerated" with "no serious adverse events" and "no withdrawals due to adverse events." Defendants characterized IMVT-1401's completed preclinical and clinical trials as a resounding success and discussed ongoing trials in favorable terms.

4. Unbeknownst to investors, however, Defendants' rosy statements about IMVT-1401 were materially false and misleading. Contrary to Defendants' portrayal of IMVT-1401 as a "safe" drug, there was a clear and substantial risk that IMVT-1401 would cause an increase in LDL and total cholesterol levels and increase the risk of heart disease. While Defendants spoke positively about the preclinical trials for IMVT-1401, they failed to disclose that the cholesterol levels of animals given IMVT-1401 were substantially elevated compared to those which were not. Defendants also failed to disclose that there were other independent reasons why IMVT-1401 could increase the cholesterol levels in humans, including scientific studies and reports of which Defendants should have been aware. Immunovant, however, in violation of FDA guidelines and Good Clinical Practices, failed to design its clinical studies to test for and report on cholesterol levels.

5. Specifically, Defendants misrepresented and failed to disclose to investors during the Class Period, among other things, that: (i) IMVT-1401 was less safe than the Company had led investors to believe; (ii) there was an anticipated risk that IMVT-1401 would substantially increase LDL and total cholesterol levels; (iii) Immunovant failed to test and/or report for the anticipated

risks and adverse events of elevated LDL or cholesterol levels in any of its Phase 1 or 2a clinical trials; (iv) Immunovant failed to follow FDA regulations and Good Clinical Practices in connection with IMVT-1401; (v) the undisclosed safety issues of substantially elevated LDL and total cholesterol levels, if publicly disclosed, threatened to delay and/or derail IMVT-1401's prospects for commercial viability and profitability; and (vi) Immunovant's business, operations and financial condition was not as represented.

6. Defendants' positive statements about Immunovant and IMVT-1401 caused an artificial inflation in the price of Immunovant securities and pushed it above certain price thresholds enabling Defendants Roivant and Wong (and others) to receive up to 20 million additional shares in the Company. The price of Immunovant stock reached a high of $50.67 during the Class Period. While Immunovant stock was artificially inflated, Immunovant and several selling shareholders, including entities controlled by Defendant Wong, registered securities for sale in several follow-on and shelf offerings, including a follow-on offering on or about September 2, 2020. As alleged below, the offering documents for the September 2, 2020 offering contained untrue statements of material fact and omitted material information about the safety and viability of IMVT-1401.

7. The first clinical trial Immunovant designed to test cholesterol levels was called the ASCEND GO-2 Phase 2b trial. On February 2, 2021, Immunovant announced it halted that study because of substantial elevations in cholesterol for patients who took IMVT-1401. Following the Company's February 2, 2021 announcement, the price of Immunovant stock collapsed from a closing price of $43.30 per share on February 1, 2021 to a closing price of $25.08 per share on February 2, 2021, a one day decline of $18.22 per share, or 42.08%, on extremely heavy trading volume of 11.76 million shares. On June 1, 2021, Immunovant announced additional details about the elevated levels of cholesterol, including that there was a link between IMVT-1401 and

cholesterol. Following the Company's June 1, 2021 announcements, the price of Immunovant stock fell from a closing price of $15.16 per share on Friday, May 28, 2021, to a closing price of $9.40 per share on June 1, 2021, a one day decline of $5.76 per share, or 38%, on extremely heavy trading volume of 16.91 million shares.

JURISDICTION AND VENUE

8. The claims asserted herein arise under and pursuant to Sections 11, 12(a)(2) and 15 of the Securities Act [15 U.S.C. §§77k, 77l(a)(2) and 77o], Sections 10(b) and 20(a) of the Exchange Act [15 U.S.C. §§78j(b) and 78t(a)] and Rule 10b-5 promulgated thereunder [17 C.F.R. §240.10b-5].

9. This Court has jurisdiction over this action pursuant to Section 22 of the Securities Act [15 U.S.C. §77v], Section 27 of the Exchange Act [15 U.S.C. §78aa], and 28 U.S.C. §§1331 and 1337.

10. Venue is properly laid in this District pursuant to Section 22 of the Securities Act, Section 27 of the Exchange Act, and 28 U.S.C. §1391(b) and (c). The acts and conduct complained of herein occurred in substantial part in this District, and the September 2020 Offering was marketed in this District.

11. In connection with the acts and conduct alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephonic communications and the facilities of the national securities markets.

BASIS OF ALLEGATIONS

12. The allegations herein are based upon the investigation conducted by and under the supervision of Plaintiff's counsel, which included interviewing former Immunovant employees and reviewing and analyzing information from numerous public and proprietary sources (such as LexisNexis, Dow Jones and Bloomberg, Inc.), including, *inter alia*, SEC filings, other regulatory

filings and reports, publicly available annual reports, press releases, published interviews, news articles and other media reports, reports of securities analysts, and public data related to Immunovant's testing and development of IMVT-1401, in order to obtain the information necessary to plead Plaintiff's claims with particularity where necessary.

13. Additionally, Plaintiff's counsel, with the assistance of consultants with extensive clinical, drug development, pharmacovigilance, and protocol development experience, reviewed and analyzed publicly available information about IMVT-1401 and publicly available information about the underlying conditions identified by Immunovant as indications for IMVT-1401. Plaintiff believes that further substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

14. Finally, as part of their investigation into the facts underlying this action, counsel for Plaintiff interviewed former employees of Immunovant. The allegations made herein are based, in part, upon information and belief and are supported by the knowledge of a former employee ("FE") who has direct first-hand knowledge about Immunovant's pre-clinical and clinical testing of IMVT-1401 and the facts alleged herein. FE worked at Immunovant during the Class Period and has first-hand knowledge of the results of the animal testing of IMVT-1401 as well as the halting of the Company's Phase 2b trial of IMVT-1401, as announced on or about February 2, 2021.

THE PARTIES

Lead Plaintiff

15. Lead Plaintiff SEPTA acquired the common stock of Immunovant as set forth in the certification previously filed with the Court and incorporated by reference herein during the Class Period and pursuant and/or traceable to the September 2020 Offering, and was damaged thereby.

Defendants

16. Defendant Immunovant is a Delaware corporation with principal executive offices located at 320 West 37th Street, New York, New York 10018. The Company's common stock trades in an efficient market on the NASDAQ under the ticker symbol "IMVT." Prior to the Merger, the Company (*i.e.*, HSAC) was a Delaware corporation with principal executive offices located at 412 West 15th Street, Floor 9, New York, New York 10011, and its securities traded on the NASDAQ under the ticker symbols "HSACU," "HSAC," and "HSACW."

17. Defendant Roivant Sciences Ltd. ("Roivant") is an integrated pharma-tech business which founds and funds biopharmaceutical and health technology companies. Defendant Roivant was a controlling shareholder of the Company at all times relevant herein. Legacy Immunovant was initially a division of Roivant. Roivant owned more than 57% of Immunovant's outstanding common stock just prior to the September 2020 Offering.

18. Defendant Peter Salzmann, M.D. ("Salzmann") has served as Immunovant's Principal Executive Officer and Chief Executive Officer ("CEO") since June 2019. Defendant Salzmann served as a member of the Company's board of directors since October 2019. Prior to Immunovant, Salzmann was Head of U.S. Immunology at Eli Lilly from May 2013 through October 2018. Defendant Salzmann signed or authorized the signing of the September 2020 Offering Registration Statement.

19. Defendant Pamela Yanchik Connealy ("Connealy") served as Chief Financial Officer ("CFO") of Immunovant from November 2019 until her resignation in July 2021. Prior to joining Immunovant, from August 2018 through November 2019, Defendant Connealy served as the CFO, Chief Operating Officer, and Chief Human Resources Officer of Kiva Microfunds. Defendant Connealy signed or authorized the signing of the September 2020 Offering Registration Statement.

20. Defendant Roderick Wong ("Wong") served as Health Sciences Acquisitions Corporation's President and CEO beginning in January 2019, and as Chairman of the board of directors since Health Sciences Acquisitions Corporation's inception in December 2018, both prior to the merger with Legacy Immunovant. Wong resigned as CEO of HSAC following the closing of the merger in December 2019. Defendant Wong served as Managing partner and Chief Investment Officer at RTW Investments, L.P. ("RTW"), a healthcare-focused investment firm, since 2010. Defendant Wong is also involved in other RTW Entities including RTW Master Fund, Ltd., RTW Innovation Master Fund, Ltd., and RTW Venture Fund Limited, where he has dispositive and voting powers over shares owned by these entities.

21. The Defendants referenced above in ¶¶18-20 are referred to herein as the "Exchange Act Individual Defendants."

22. Defendant Frank M. Torti, M.D. ("Torti") served as Chairperson of the Board of Directors of Immunovant during the Class Period. Defendant Torti signed or authorized the signing of the September 2020 Offering Registration Statement.

23. Defendant Andrew Fromkin ("Fromkin") served as a director of Immunovant during the Class Period. Defendant Fromkin signed or authorized the signing of the September 2020 Offering Registration Statement.

24. Defendant Douglas Hughes ("Hughes") served as a director of Immunovant during the Class Period. Defendant Hughes signed or authorized the signing of the September 2020 Offering Registration Statement.

25. Defendant George Migausky ("Migausky") served as a director of Immunovant during the Class Period. Defendant Migausky signed or authorized the signing of the September 2020 Offering Registration Statement.

26. Defendant Atul Pande, M.D. ("Pande") served as a director of Immunovant during the Class Period. Defendant Pande signed or authorized the signing of the September 2020 Offering Registration Statement.

27. Defendant Eric Venker, M.D., Pharm. D., ("Venker") served as a director of Immunovant during the Class Period. Defendant Venker signed or authorized the signing of the September 2020 Offering Registration Statement.

28. The Defendants referenced above in ¶¶18-19, 22-27 are referred to herein as the "Securities Act Individual Defendants."

29. Defendant SVB Leerink LLC ("SVB Leerink") operates as an investment bank specializing in healthcare and technology with its principal executive offices located in Boston, MA. SVB Leerink acted as a lead underwriter, joint bookrunning manager, and served as representative for the underwriters for the September 2020 Offering and helped to draft and disseminate the Prospectus for the September 2020 Offering.

30. Defendant LifeSci Capital LLC ("LifeSci") is a boutique investment bank focusing on life sciences located in New York, NY. LifeSci acted as an underwriter for the September 2020 Offering and helped to draft and disseminate the Prospectus for the September 2020 Offering.

31. Defendant Chardan Capital Markets LLC ("Chardan") is a global investment bank with its principal executive offices located in New York, NY. Chardan acted as an underwriter and joint bookrunning manager for the September 2020 Offering. Chardan helped to draft and disseminate the Prospectus for the September 2020 Offering.

32. Defendant Guggenheim Securities, LLC ("Guggenheim") operates as a global investment and advisory firm with its principal executive offices located in New York, NY. Guggenheim acted as a lead underwriter, joint bookrunning manager, and served as representative

for the underwriters for the September 2020 Offering and helped to draft and disseminate the Prospectus for the September 2020 Offering.

33. Defendant Robert W. Baird & Co. Incorporated ("Robert W. Baird") is a global investment bank and financial services company with its principal executive offices located in Milwaukee, WI. Robert W. Baird acted as an underwriter for the September 2020 Offering and helped to draft and disseminate the Prospectus for the September 2020 Offering.

34. The Defendants referenced above in ¶¶29-33 are herein collectively referred to as the "Underwriter Defendants." The Underwriter Defendants failed to perform adequate due diligence in connection with their role as underwriters for the September 2020 Offering and were negligent in failing to ensure that the Registration Statement and Prospectus for the September 2020 Offering were prepared properly and accurately. The Underwriter Defendants' failure to conduct an adequate due diligence investigation was a substantial factor leading to the harm complained of herein.

35. The Underwriters who drafted and disseminated the September 2020 Offering documents were paid approximately $12 million in gross fees in connection therewith.

36. Defendants Immunovant, Roivant, the Securities Act Individual Defendants, the Exchange Act Individual Defendants, and the Underwriter Defendants are collectively referred to herein as "Defendants."

CLASS ACTION ALLEGATIONS

37. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Immunovant securities pursuant and/or traceable to the September 2020 Offering, as well as purchasers of the Company's securities during the Class Period (the "Class"); and were damaged thereby. Excluded from the Class are Defendants herein, the officers and directors of the Company,

at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

38. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Immunovant securities were actively traded on the NASDAQ and Immunovant sold more than 6 million shares of common stock in the September 2020 Offering. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Immunovant or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

39. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

40. Plaintiff will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

41. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether the Prospectus and Registration Statement issued by Defendants to the investing public in connection with the September 2020 Offering negligently omitted and/or misrepresented material facts about Immunovant and its business;

- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Immunovant;
- whether the Exchange Act Individual Defendants caused Immunovant to issue false and misleading financial statements during the Class Period;
- whether the Exchange Act Individual Defendants and the Company acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of Immunovant securities during the Class Period were artificially inflated because of Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

42. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

43. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- Immunovant securities are traded in an efficient market;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiff and members of the Class purchased, acquired and/or sold Immunovant securities between the time the Defendants failed to disclose or misrepresented

material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

44. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

45. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

SUBSTANTIVE ALLEGATIONS

The Company and Its Business

46. Immunovant is a clinical-stage biopharmaceutical company that develops monoclonal antibodies for the treatment of autoimmune diseases. Autoimmune diseases are conditions where an immune response is inappropriately directed against the body's own healthy cells and tissues. At all times relevant during the Class Period, Immunovant was developing a novel, fully human monoclonal antibody, IMVT-1401 (formerly referred to as RVT-1401), that selectively binds to and inhibits the neonatal fragment crystallizable receptor, or FcRn. Immunovant was developing IMVT-1401 as a fixed-dose, self-administered subcutaneous injection with an initial focus on the treatment of myasthenia gravis, or "MG," thyroid eye disease, or "TED" (also known as Graves' ophthalmopathy, or "GO"), and Warm Autoimmune Hemolytic Anemia, or "WAIHA."

47. Immunovant was named Immunovant Sciences Ltd. when it was a private company, Legacy Immunovant, and was a business unit of Roivant. Legacy Immunovant became a public company when it was acquired by a special purpose entity, or "SPAC," named Health Sciences Acquisitions Corporation ("HSAC"). A SPAC is a blank check company formed solely to raise capital through an initial public offering ("IPO") and then use the money to acquire businesses

thereafter. Money raised during the SPAC's IPO is commonly placed in a trust account until a certain amount of time passes or the SPAC enters a business combination. The SPAC founders have a financial stake in finding a company to acquire because they invest capital and receive shares in the SPAC and if an acquisition is not made within a specified time period (*i.e.*, within 18 to 24 months) the SPAC is typically dissolved, and the capital raised from the IPO must be returned to investors.

48. HSAC was a blank check company formed for the purpose of effecting a merger, asset acquisition, or similar business combination. It was HSAC's intention to pursue prospective targets focused on healthcare innovation. Health Sciences Holdings, LLC ("HSH") was HSAC's sponsor, was operated by Defendant Wong, and was an affiliate of RTW, which was a New York financial firm, Defendant Wong also controlled. Defendant Wong formed RTW in 2009 and focused on investing in the healthcare industry across the life sciences space and supported companies through the FDA approval process and the commercialization of drugs.

49. HSAC raised approximately $115 million from investors in its IPO on or about May 9, 2019. The proceeds from the IPO were deposited into a trust account for the benefit of the public shareholders. In connection with the IPO, HSAC's sponsor (HSH) acquired 10 million convertible warrants for $5 million. HSAC had 24 months from the closing of its IPO in May 2019 to consummate a transaction. If HSAC failed to do so, it would have had to redeem 100% of its outstanding public shares, liquidate and dissolve. Upon dissolution, any public warrants would expire and all proceeds from the IPO would be returned to public shareholders.

50. On September 29, 2019, HSAC entered into an agreement with Legacy Immunovant, and shareholders of Legacy Immunovant, to effect a merger between the two entities. Defendant Roivant and Defendant Wong, through RTW, were shareholders of Legacy Immunovant. On October 2, 2019, HSAC and Legacy Immunovant announced in a press release (the "10/2/19 Press

Release") that they entered into a definitive share exchange agreement ("SEA") under which HSAC would acquire 100% of the issued and outstanding shares of Legacy Immunovant. As described in the 10/2/19 Press Release, upon the closing of the transactions, the Legacy Immunovant shareholders will sell to HSAC all of the issued and outstanding Legacy Immunovant shares, and HSAC will issue (or reserve for issuance upon the exercise of options) approximately 43 million HSAC shares to the current Immunovant shareholders. The aggregate value of the consideration to be paid by HSAC in the business combination was more than $421 million. Upon consummation of the merger, Legacy Immunovant became a wholly owned subsidiary of HSAC, and HSAC changed its name to "Immunovant Inc."

51. After the merger, depending upon the exercise of redemption rights by certain shareholders, HSAC's public stockholders prior to the merger were expected to own between 13.8% to 21% of HSAC's non-redeemable shares, HSAC's directors, officers and affiliates were expected to own approximately 2% to 2.1% of HSAC's non-redeemable shares, and the shareholders of Legacy Immunovant were expected to own between 77% to 84.1% of HSAC's non-redeemable shares. Additionally, Legacy Immunovant shareholders were entitled to receive additional shares in Immunovant based on the price of Immunovant common stock. As described in the 10/2/19 Press Release:

> [Legacy] Immunovant shareholders may, subject to the terms of the SEA, receive up to an additional 20 million HSAC shares (the "Earnout Shares"): ***10 million shares if the share price exceeds $17.50 by March 31, 2023 and an additional 10 million shares if the share price exceeds $31.50 by March 31, 2025***…Furthermore, subject to terms of the SEA, ***1.8 million of the sponsor's founder shares will be cancelled unless HSAC's common stock exceeds certain stock prices on substantially identical terms and conditions as the Earnout Shares***.

(Emphasis added).

52. The merger between HSAC and Legacy Immunovant was approved on December 16, 2019. As a result of the Merger, HSAC acquired all the issued and outstanding shares of Legacy

Immunovant, and Legacy Immunovant became a wholly owned subsidiary of HSAC. Upon the closing of the Merger, HSAC changed its name to "Immunovant, Inc."

53. HSAC or its sponsor had interacted with Legacy Immunovant for nearly one year prior to the approval of the transaction. On December 28, 2019, RTW purchased more than 2.6 million Legacy Immunovant shares, representing approximately 3% interest in Legacy. On May 11, 2019, Defendant Wong, who was CEO of HSAC at the time, contacted Mayukh Sukhatme, a Legacy Immunovant director and the President of Roivant, to discuss the possibility of a transaction between HSAC and Legacy Immunovant. On July 31, 2019, after back and forth communications for months, the parties entered into a letter of intent for the transaction. Between August 1, 2019 and September 20, 2019, HSAC continued its review of due diligence materials and HSAC, Legacy Immunovant, and the sellers of Legacy Immunovant entered into the Share Exchange Agreement for HSAC's merger with Legacy Immunovant.

The FDA Drug Testing and Approval Process

54. The process of drug development in the U.S. and elsewhere follows a standard sequence of experimental phases. The FDA regulates the sale and marketing of pharmaceutical products in the United States. The FDA reviews new drugs through New Drug Applications ("NDA"). Prior to approval, a drug typically goes through the pre-clinical and clinical trial stages. The NDA for a particular drug is based on data obtained through clinical trials conducted by the drug company pursuant to FDA guidelines. The Clinical trials have three phases – Phase I, II, III – which must be successfully completed before submission of an NDA to the FDA.

55. Before the clinical trial stage, nonclinical studies precede human experimentation to develop a basic understanding of toxicity and potential adverse effects associated with the use of the drug, as well as to define potential dosages to be used in humans. A standard battery of tests are

performed to determine organ toxicity, effects on the fetus, damage to DNA, and potential "off-target" effects.

56. The procedures for clinical trials and sponsor requirements are described in Title 21, Subchapter D of the Code of Federal Regulations. Part 312 describes the requirements for drugs studied under an Investigational New Drug ("IND") application. Prior to initiating any clinical trials involving human subjects, an IND application must be filed. Upon completion of the nonclinical (or preclinical) studies, the sponsor may also meet with the FDA for a pre-IND meeting. One of the purposes of this meeting is to discuss the rationale for safety monitoring based on the pharmacology and toxicology results known at that time. As an example, if elevations in cholesterol were noted in animal studies, it would be important for the sponsor to discuss with the FDA the proposed pharmacovigilance plan and its rationale.[1] After submission of the first in human (FIH) study protocol, the FDA has 30 days to review the protocol before the study can be initiated in humans.

57. Phase 1 studies are designed to assess safety, typically in healthy volunteers. The studies will begin with single doses in ascending dose strength. Once a tolerable dose range is established, multiple doses are given to subjects to assess both safety and the pharmacokinetics of the drug in humans.[2]

58. Following Phase 1 studies, the sponsor will traditionally begin Phase 2 studies. These are studies in patient populations (such as myasthenia gravis or thyroid eye disease) and are primarily designed to determine an appropriate dose range for larger, Phase 3, or pivotal, studies.

[1] Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem.

[2] Pharmacokinetics is the study of the time course of drug absorption, distribution, metabolism, and excretion.

Safety should be carefully assessed during Phase 2 studies for signals of potential adverse reactions, particularly those that are severe and/or dose related.

59. Phase 3 studies are larger studies involving a broader population of patients with the disorder under study. These studies are considered pivotal for evidence of efficacy and safety by the FDA and, typically, two "adequate and well-controlled" studies are required by the FDA for review and approval.

60. Ultimately, the FDA has the final authority to determine the balance of (potential) benefits and risks in drugs under development and the Agency may impose a Partial or Complete Clinical Hold if a significant safety issue is identified. Therefore, it is incumbent upon the sponsor to conduct studies in compliance with CFR 312 and Good Clinical Practices, as defined in the International Conference on Harmonization (ICH) E6, in order to protect patients to the extent possible. An important part of that protection involves ongoing surveillance of adverse events[3] and suspected adverse reactions.[4]

Immunovant Was Required to Assess the Safety of IMVT-1401 Before and During Clinical Trials

61. The World Health Organization defines pharmacovigilance as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem." Pharmacovigilance is a process that requires regular and ongoing surveillance of safety data received during the conduct of a clinical trial. Commonly

[3] "Adverse event means any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related." U.S. Code of Federal Regulations, Title 21, Sec. 312.32(a).

[4] "Suspected adverse reaction means any adverse event for which there is a reasonable possibility that the drug caused the adverse event. For the purposes of IND safety reporting, 'reasonable possibility' means there is evidence to suggest a causal relationship between the drug and the adverse event." U.S. Code of Federal Regulations, Title 21, Sec. 312.32(a).

accepted PV practices were described by the Council for International Organizations of Medical Sciences (CIOMS) in CIOMS VI.

62. During the conduct of clinical trials, the sponsor is required to monitor and assess safety information on an ongoing basis, looking for the emergence of any new risks. These may be anticipated to occur in the patient population being studied (for example, stroke in a study of patients with atrial fibrillation) but imbalances between the treated group and the control group might suggest a greater risk associated with the drug. Furthermore, adverse events reported in other drugs within a pharmacological class or within the same drug in animal studies should lead to a heightened level of surveillance for anticipated risks, as described by the CIOMS VI Working Group:

> The CIOMS VI Working Group considers the term "known risk" to refer to a risk that has been observed and is reasonably established for the investigational product itself; the term "anticipated risk" to refer to a risk that has not yet been observed or established for the product but is expected to occur based on knowledge of the class of drugs; and the term "potential risk" to refer to a risk that has not yet been observed in humans for the investigational product itself or for other drugs in the class but for which there is reason to suspect it might occur, based on animal toxicology studies or the known pharmacologic properties. In other contexts (e.g., ICH E2E), what we refer to as anticipated risks are usually placed in the potential risk category.

63. If new safety issues are identified, the sponsor is required to report these issues to regulatory authorities. When developing drugs under an IND, sponsors must adhere to the requirements for safety reporting as described in CFR 312.32. A Guidance for Industry was published by the FDA in 2005 describing IND Safety Reporting. This was updated in 2010 when the FDA published the Final Rule for IND Safety Reporting in the Federal Register. Since that time, there have been 3 Guidances and/or Draft Guidances published (December, 2012; December, 2015; and June, 2021) to clarify the FDA position regarding appropriate assessment and reporting of safety.

64. As described by the FDA in its December, 2015, Guidance for Industry and Investigators, the sponsor is required under CFR 312.32 to assess safety data from all sources, including results from animal studies. Specifically, the FDA wrote:

> The sponsor is required to review promptly all information relevant to the safety of the drug (21 CFR 312.32(b)). During the course of drug development, adverse event information is generally reported to a sponsor by investigators conducting clinical trials; however, a sponsor may become aware of new safety information from a variety of sources, both domestic and foreign. Some examples of sources are listed as follows, but safety information from any other source would also need to be reviewed and evaluated by the sponsor.
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> ***Animal studies*** or in vitro studies Clinical or epidemiological investigations; Reports in the ***scientific literature***; Unpublished scientific papers; Information presented at scientific meetings; Reports from foreign regulatory authorities; Reports from commercial marketing experience; Safety information presented at a professional meeting; Foreign spontaneous reports.
>
> The sponsor's review should include examining data from all sources and deciding whether the information meets the criteria for expedited reporting (see section V), as well as evaluating all accumulating data at regular intervals to update safety information and to identify new safety signals. Some types of information should be sought by the sponsor as part of its continuous pharmacovigilance on the safety of the drug. For example, the ***sponsor should conduct literature searches regularly*** with a frequency appropriate to the drug or study design ***to seek safety information*** and report that information if necessary.

(Emphasis added).

65. Accordingly, pursuant to CFR 312.32, Immunovant was required to review the safety data from the IMVT-1401 animal studies and regularly search for and review potential safety issues with IMVT-1401 in the scientific literature and other sources.

66. In early clinical development phases, little may be known about safety in humans and, therefore, the results of animal studies are important for the identification of potential and/or anticipated risks. The FDA published the Guidance for Industry describing ICH M3 (R2) (Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals), stating, in pertinent part, as follows:

> The development of a pharmaceutical is a stepwise process involving an evaluation of both animal and human efficacy and safety information. The goals of the nonclinical safety evaluation generally include a characterization of toxic effects with respect to target organs, dose dependence, relationship to exposure, and, when appropriate, potential reversibility. This information is used to estimate an initial safe starting dose and dose range for the human trials and to ***identify parameters for clinical monitoring for potential adverse effects***. The nonclinical safety studies, although usually limited at the beginning of clinical development, should be ***adequate to characterize potential adverse effects that might occur under the conditions of the clinical trial to be supported***.

(Emphasis added).

67. Similarly, the FDA Guidance for Industry regarding ICH S7a (Safety Pharmacology Studies for Human Pharmaceuticals), states, in pertinent part, the following:

> The objectives of safety pharmacology studies are (1) to identify undesirable pharmacodynamic properties of a substance that may have relevance to its human safety, (2) to evaluate adverse pharmacodynamic and/or pathophysiological effects of a substance observed in toxicology and/or clinical studies, and (3) to investigate the mechanism of the adverse pharmacodynamic effects observed and/or suspected. ***The investigational plan to meet these objectives should be clearly identified and delineated***.

(Emphasis added).

68. The S7a Guidance document further notes:

> Since pharmacological effects vary depending on the specific properties of each test substance, the studies should be selected and designed accordingly. The following factors should be considered (the list is not comprehensive).
>
> 1. Effects related to the therapeutic class of the test substance, since the mechanism of action may suggest specific adverse effects (e.g., proarrhythmia is a common feature of antiarrhythmic agents)
>
> 2. Adverse effects associated with members of the chemical or therapeutic class, but independent of the primary pharmacodynamic effects (e.g., antipsychotics and QT prolongation)
>
> 3. Ligand binding or enzyme assay data suggesting a potential for adverse effects
>
> 4. Results from previous safety pharmacology studies, from secondary pharmacodynamic studies, from toxicology studies, or from human use that warrant further investigation to establish and characterize the relevance of these findings to potential adverse effects in humans.

69. Thus, safety and toxicology findings from nonclinical studies are important guideposts for the development of a safety surveillance or pharmacovigilance plan. These nonclinical safety findings are particularly important in early phase clinical studies when fewer patients have been treated and direct information on tolerability in humans is available.

Immunovant's Pre-Clinical Animal Studies Showed that IMVT-1401 Substantially Raised the Cholesterol Levels of Animals

70. Immunovant performed animal studies on IMVT-1401. According to FE, Immunovant measured the cholesterol levels in the animals which were part of the study. The animal studies listed the cholesterol of the animals at the start of the test and at the end of the test and those results clearly showed a substantial increase in the cholesterol of the animals that received IMVT-1401. According to FE, cholesterol and triglycerides were significantly increased for animals which received IMVT-1401 compared to those that were not. In fact, some of the animals showed cholesterol levels of 200 to 300 percent higher when compared with the control group of animals which never received IMVT-1401. FE recalled that each of the animal studies FE reviewed revealed increases in cholesterol for the animals that took IMVT-1401.

71. Since the animal studies for IMVT-1401 clearly showed that the LDL and cholesterol levels of animals which received IMVT-1401 were substantially increased, Immunovant should have known that there was a substantial risk that IMVT-1401 would also increase the LDL and total cholesterol levels of humans. As a result, Immunovant should have designed all clinical trials in humans to include a standard cholesterol panel to test the subjects' cholesterol profile (total cholesterol, LDL cholesterol, HDL cholesterol, and triglycerides). As admitted by Immunovant on February 2, 2021, unbeknownst to investors and the market, Immunovant failed to test the cholesterol in any phase 1 or phase 2 clinical trials prior to the ASCEND GO-2 Phase 2b test that was halted by the Company as announced on February 2, 2021.

72. Finally, upon information and belief, Defendant Immunovant failed to inform the FDA that its animal studies substantially increased the cholesterol of animals that were dosed with IMVT-1401 compared with the control group of animals. According to FE, the reports for the animal studies contained detailed information showing the increases in cholesterol levels. While the reports conclusively showed that cholesterol levels increased for animals taking IMVT-1401, the summary portion of the reports indicated that there were only minor increases in cholesterol. Upon information and belief, the description of the animal studies provided by Immunovant to the FDA falsely stated that there was only a minor increase in cholesterol for animals taking IMVT-1401 compared with the control group that did not take IMVT-1401.

Studies Have Widely Reported that FcRn Inhibition and Reduced Serum Albumin Levels, Such as Caused by IMVT-1401, Impact Cholesterol and Increase Risk for Cardiovascular Disease

73. It is widely known in the medical community that elevated lipids, in particular LDL cholesterol, are associated with cardiovascular disease, as defined in a 1992 study referred to as the Framingham Heart Study. It has also been reported in medical journals and studies for years before the start of the Class Period that a lack of FcRn and/or lower serum albumin levels impacts cholesterol levels.

74. A 2002 study by Djoussé L et al., titled *Serum albumin and risk of myocardial infarction and all-cause mortality in the Framingham Offspring Study*, (the "Framingham Offspring Study") reported that lower serum albumin concentrations were associated with an increased risk of coronary artery disease in both sexes and with all-cause mortality in women. The association between elevated lipids, in particular LDL cholesterol, and cardiovascular disease were clearly defined in the Framingham Offspring Study using a tercile approach to albumin levels, hazard ratios 31 observed for myocardial infarction were 1.0, 1.25, and 1.49 for men and 1.0, 1.79, and 2.12 for women, with increasing risk seen in patients with lower concentrations of serum albumin.

75. A 2012 study titled *Clinical chemistry of human FcRn transgenic mice* by C. Stein et al., reported the results of FcRn alterations using transgenic and FcRn knockout mice and observed effects on clinical chemistry parameters.[5] Compared with controls, ***mice that lacked FcRn (mFcR-/; genetic modification leading to lack of FcRn) had statistically significantly higher levels of cholesterol, LDL cholesterol and HDL cholesterol***. Of the three parameters, LDL cholesterol increased in female knockout mice by approximately 66% (0.5 mmol/L in knockout vs. 0.3 mmol/L in controls) compared with control (C57BL/6J) mice. Male knockout mice were observed to have a 25% greater increase in LDL cholesterol compared with control mice (0.5 mmol/L vs. 0.4 mmol/L, respectively). In contrast to the increases in total cholesterol, LDL cholesterol and HDL cholesterol, knockout mice were noted to have highly statistically significantly lower albumin and total protein levels compared with controls.

76. Similar results were reported in a 2015 study titled *Albumin-deficient mouse models for studying metabolism of human albumin and pharmacokinetics of albumin-based drugs* by Roopenian et al. That study reported statistically significantly greater cholesterol levels (total, LDL, HDL) in two different knockout mice models. ***Compared with controls, LDL cholesterol levels were increased approximately two-fold in one model and four-fold in the other***.

77. IMVT-1401 (also referred to as batoclimab), is a neonatal FC receptor (FcRn) inhibitor that results in a decrease in immunoglobulin ("IgG"). HanAll BioPharma, a Korean company, developed the compound as HL-161 and later licensed rights for development of the compound to Defendant Roivant (when it was referred to as RVT-1401) and ultimately Immunovant (when it was changed to IMVT-1401). IMVT-1401 is in a class of drugs being researched by

[5] A knockout mouse is a laboratory mouse in which researchers have inactivated, or "knocked out," an existing gene by replacing it or disrupting it with an artificial piece of DNA.

several sponsors in multiple therapeutic areas, including Argenx SE, Alexion Pharmaceuticals, and UCB. Diseases targeted in clinical trials by these sponsors, including Immunovant, include myasthenia gravis, idiopathic thrombocytopenic purpura (ITP), warm autoimmune hemolytic anemia (WAIHA), pemphigus vulgaris, thyroid eye disease (TED, also known as Grave's ophthalmopathy), chronic idiopathic demyelinating polyneuropathy (CIDP), and neuromyelitis optica.

78. The conditions targeted by the Company with IMVT-1401, such as myasthenia gravis and Grave's disease, result from aberrant targeting of "self" by the immune system (termed autoimmune diseases). As alleged above, IMVT-1401 selectively binds to and inhibits the neonatal fragment crystallizable receptor, or FcRn. Neonatal Fc Receptor (FcRn) binding leads to internalization of immunoglobulin (IgG) and albumin and, in so doing, protects these compounds from degradation, thus increasing their half-lives. Reductions in circulating immunoglobulin (IgG) are postulated to improve the autoimmunity and, hence, improve the clinical condition.

79. While FcRn treatment may potentially be effective against the targeted medical conditions, there are also risks associated with the reduction in serum albumin levels, including the risk of cardiovascular disease and an increase in lipid levels.

Thyroid Hormone Levels, Such as the Levels Impacted by Grave's Ophthalmopathy, Are Connected to Cholesterol Levels

80. The association between thyroid hormone levels and cholesterol were also well established prior to the start of the Class Period. In fact, a study published in 1930 titled *Blood cholesterol values in hyperthyroidism and hypothyroidism - their significance* in The New England Journal of Medicine by Mason, RL et al., as well as additional literature and studies, including a 2011 study titled, *Effects of thyroid dysfunction on lipid profile* in The Open Cardiovascular Medicine Journal by Rizos, CV et al., have made clear there is an inverse relationship between thyroid function and cholesterol.

81. Since Grave's Ophthalmopathy is a thyroid condition, and since thyroid levels are known to impact cholesterol levels, the treatment of Grave's Ophthalmopathy would also be expected to impact cholesterol levels. In fact, as reported in a 2020 study titled *Treatment of Thyroid Dysfunction and Serum Lipids: A Systematic Review and Meta-Analysis* in The Journal of Clinical Endocrinology & Metabolism by Kotwal, A et al., treatment of hyperthyroidism was found to increase cholesterol levels.

There Was an Undisclosed Anticipated Risk that IMVT-1401 Would Increase the Cholesterol and Risk of Heart Disease in Patients

82. Elevations in serum cholesterol are known to be associated with an increased risk of vascular disease and overall mortality. Due to the studies and reports concerning FcRn and elevated cholesterol as a result of reductions in albumin, clinical observations in humans, including those with thyroid disease, and the results of IMVT-1401's animal studies, increased cholesterol was an anticipated risk in clinical studies of IMVT-1401 for the following reasons:

(a) Treatment with FcRn inhibitors, such as IMVT-1401 will potentially lower serum albumin levels. As a result of the decrease in serum albumin levels, serum cholesterol (total and LDL) levels may increase;

(b) Conditions such as myasthenia gravis and Grave's Ophthalmopathy would likely require chronic therapy with FcRn inhibitors. Treatment of Grave's Ophthalmopathy will result in lowered thyroid hormone levels. This will lead to increased serum cholesterol (both total and LDL) levels. If therapy is associated with increased lipids, particularly LDL cholesterol, the patient's risk of cardiovascular disease would be increased; and

(c) Immunovant's animal study revealed an increase in cholesterol in the tested animals.

83. Indeed, other companies developing similar compounds, including Harbour BioMed, the license holder for 1401 in Greater China, and competitor Argenx SE, tested for cholesterol, showing that those entities recognized that elevated cholesterol levels were an anticipated risk that needed to be monitored.

Even Though Increased Cholesterol Was an Anticipated Risk of IMVT-1401, Immunovant Failed to Test or Report on Cholesterol in Any Clinical Studies Prior to the ASCEND GO-2 Phase 2b Trial Which Was Halted at the End of the Class Period

84. Immunovant conducted a phase 1 trial of IMVT-1401 and the results of that study were published in the journal Neurology on April 9, 2019. Unbeknownst to investors, Immunovant failed to test for cholesterol levels during that phase 1 study. Immunovant minimized any adverse events from the phase 1 study, stating, in pertinent part, as follows: "All adverse events (AEs) were mild to moderate in severity, with no subjects requiring premature discontinuation due to AEs."

85. Immunovant registered four phase 2 clinical trials on clinicaltrials.gov targeting thyroid eye disease, myasthenia gravis, and warm autoimmune hemolytic anemia.

86. A 17-patient study of RVT-1401 treatment in patients with myasthenia gravis was initiated on May 21, 2019 and completed on December 21, 2020, comparing 680 mg RVT-1401, 340 mg RVT-1401, or placebo in a parallel fashion. The study was unblinded after 15 patients completed treatment and top line results were reported in a press release on August 25, 2020. The Company reported the efficacy results as being potentially "best-in-class," stating, in pertinent part, as follows: "The clinical benefits we observed in this trial provide strong support that IMVT-1401 might ultimately become a best-in-class anti-FcRn agent for MG patients..." Additionally, Immunovant stressed that IMVT-1401 was "safe," stating, in pertinent part, as follows: "Consistent with previously reported Phase 1 results, IMVT-1401 was observed to be generally safe and well-tolerated with no serious adverse events (SAEs), no withdrawals due to adverse events (AEs), and no

imbalance in headaches." Immunovant, however, failed to test for the impact of IMVT-1401 on cholesterol.

87. On February 29, 2020, Immunovant began the Phase 2a study of Grave's ophthalmopathy (thyroid eye disease), ASCEND-GO 1, a seven-patient study, which was completed on May 21, 2020, of RVT-1401 680 mg subcutaneously (SQ) every week for 2 weeks, followed by 340 mg SQ every week for 4 weeks. Although some study results are posted on clinicaltrials.gov, no laboratory data is described and the only adverse event in the Investigations System Organ Class (SOC) is Weight gain. One hundred percent of study participants had at least one adverse event. Lacrimation increased (2/7), Dizziness (2/7), and Fatigue (2/7) were the only adverse events reported in more than one patient. Once again, unbeknownst to investors, Immunovant did not test for changes in cholesterol.

88. The first time Immunovant tested for cholesterol was in the ASCEND GO-2 Phase 2b trial which was halted, as announced by the Company on February 2, 2021.

89. Testing for cholesterol levels is inexpensive and simply requires a blood test. Since increased cholesterol levels were an anticipated risk of treatment with IMVT-1401, in accordance with good clinical practices and standards, Immunovant should have designed each of the phase 1 and 2 clinical trials so that the cholesterol for each of the participants was tested and monitored. Unbeknownst to investors, however, Immunovant failed to test the cholesterol levels of the clinical trial participants during the IMVT-1401 Phase 1 or 2 clinical trials prior to the ASCEND GO-2 Phase 2b clinical trial.

90. The Company admitted in a press release on February 2, 2021, that cholesterol levels were not measured in prior clinical trials of IMVT-1401, stating, in pertinent part, as follows:

> The Company has become aware of a physiological signal consisting of elevated total cholesterol and LDL levels in IMVT-1401-treated patients in ASCEND GO-2, a

> Phase 2b trial in Thyroid Eye Disease (TED). ***Cholesterol levels were not measured in prior clinical trials of IMVT-1401 in Myasthenia Gravis (MG) and in healthy subjects.*** Out of an abundance of caution, the Company has decided to voluntarily pause dosing in ongoing clinical studies in both TED and in Warm Autoimmune Hemolytic Anemia, in order to inform patients, investigators, and regulators as well as to modify the monitoring program.

(Emphasis added).

91. Since elevated cholesterol levels were an anticipated risk, and since the cholesterol levels of clinical trial participants were not being tested prior to Immunovant's ASCEND GO-2 Phase 2b clinical trial, statements about the safety and viability of IMVT-1401 prior to this time omitted material information and were misleading.

THE SEPTEMBER 2020 OFFERING DOCUMENTS CONTAINED INACCURATE STATEMENTS OF MATERIAL FACT AND OMITTED MATERIAL INFORMATION REQUIRED TO BE DISCLOSED THEREIN

92. On or about August 31, 2020, Immunovant filed a Form S-1 Registration Statement with the SEC for a follow on offering of securities. On or about September 1, 2020, the Prospectus with respect to the follow-on offering, which forms part of the Registration Statement, became effective and on or about September 2, 2020 (until on or about September 4, 2020), more than 5.27 million shares of common stock of Immunovant at $33.00 per share were sold to the public, thereby raising $163.7 million. The August 31, 2020 Registration Statement and September 1, 2020 Prospectus are collectively referred to herein as the "Sept. 2020 Offering Documents."

93. In addition to the above-referenced 5.27 million shares, the September 2020 Offering included an overallotment option granted to the Underwriters to purchase up to an additional 790,513 shares of common stock and the Underwriters fully exercised this option on September 4, 2020. In total, 6,060,606 shares were sold in the September 2020 Offering at $33.00 per share, thereby raising approximately $200 million.

94. The Sept. 2020 Offering Documents contained untrue statements of material fact and omitted material information because they failed to disclose the following facts which existed at the time:

(a) IMVT-1401 was less safe than the Company had led investors to believe;

(b) There was an anticipated risk that IMVT-1401 would substantially increase LDL and total cholesterol levels because, among other reasons:

(i) Immunovant's animal studies for IMVT-1401 revealed a substantial increase in cholesterol for animals that received IMVT-1401;

(ii) IMVT-1401 was in a class of drug which lowered serum albumin levels, and medical journals and studies reported that low serum albumin levels increases LDL and total cholesterol levels;

(iii) Due to the effect of albumin changes on cholesterol, Immunovant should have disclosed or at least tested cholesterol levels earlier than it did;

(iv) other companies researching the same class of drug apparently recognized this risk because they tested cholesterol levels; and

(v) thyroid conditions which were indications for IMVT-1401, such as Grave's Ophthalmopathy and myasthenia gravis, are known to reduce cholesterol, so if IMVT-1401 is successful in treating the underlying thyroid condition, it should be expected that cholesterol would increase.

(c) Immunovant failed to test for the anticipated risks and adverse events of elevated LDL or total cholesterol levels in any of its phase 1 or 2 clinical trials conducted prior to its ASCEND GO-2 Phase 2b trial which was halted, as announced on February 2, 2021;

(d) Immunovant failed to follow FDA regulations and Good Clinical Practices in connection with IMVT-1401 because:

(i) it failed to perform ongoing surveillance of the adverse events and suspected adverse reactions of elevated LDL and total cholesterol levels; and

(ii) Immunovant was required to report to the FDA that its animal studies showed a substantial increase in cholesterol levels for animals taking IMVT-1401. Upon information and belief, Immunovant failed to inform the FDA of the substantial increases in cholesterol experienced by animals.

(e) The undisclosed safety issues of substantially elevated LDL and cholesterol levels, if publicly disclosed, threatened to delay and/or derail IMVT-1401's prospects for commercial viability, and profitability; and

(f) Immunovant's business, operations and financial condition were not as represented.

95. The Sept. 2020 Offering Documents discussed that Immunovant is controlled by Defendant Roivant, stating, in pertinent part, as follows:

> **Our Controlling Stockholder**
>
> ***Roivant is currently our majority stockholder, and we are a "controlled company" within the meaning of the listing rules of Nasdaq. We will remain a "controlled company" so long as 50% of the voting power for the election of directors is held by Roivant.*** As such, we are availing ourselves of certain controlled company exemptions under the Nasdaq listing rules. ***We are not required to have a majority of "independent directors" on our board of directors, as defined under the Nasdaq listing rules, or to have a compensation committee or a committee performing the director nominating function composed entirely of independent directors. Roivant will be able to exercise control over all matters requiring stockholder approval, including the election of our directors and approval of significant corporate transactions.*** In addition, Roivant, as the holder of Series A preferred stock, has the right to elect a certain number of Series A Preferred Directors in accordance with the provisions of our amended and restated charter.

(Emphasis added).

96. The Sept. 2020 Offering Documents generally described the manner in which Immunovant conducted its clinical trials, stating, in pertinent part, the following:

> Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated…
>
> - Phase 1 — The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. ***These studies are designed to test the safety***, dosage tolerance, absorption, metabolism, distribution and elimination of the investigational product in humans, the ***side effects associated with increasing doses***, and, if possible, to gain early evidence on effectiveness.
>
> - Phase 2 — The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule ***and to identify possible adverse side effects and safety risks***. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
>
> - Phase 3 — The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval. These trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing.

(Emphasis added).

97. The statements referenced above in ¶¶95-96 were each inaccurate statements of material fact when made because of the reasons set forth in ¶94 above. Additionally, the statements about Phase 1 studies being "designed to test the safety" and Phase 2 studies to "identify possible side effects and safety risks" because Immunovant had not tested for "safety," "possible adverse side effects and safety risks" related to elevated levels of cholesterol in connection with IMVT-1401.

98. The Sept. 2020 Offering Documents described that there was a lack of "safe and effective treatment options for patients suffering from autoimmune diseases" and that IMVT-1401 had already shown itself to be a safe solution for this market need, stating, in pertinent part, as follows:

> ***Unfortunately, safe and effective treatment options for patients suffering from autoimmune diseases are lacking.*** Currently available treatments are generally limited to corticosteroids and immunosuppressants in early-stage disease and intravenous immunoglobulin, or IVIg, or plasma exchange in later-stage disease. ***These approaches often fail to address patients' needs since they are limited by delayed onset of action, waning therapeutic benefit over time and unfavorable safety profiles.***
>
> * * *
>
> FcRn plays a pivotal role in preventing the degradation of IgG antibodies. The physiologic function of FcRn is to modulate the catabolism of IgG antibodies, and inhibition of FcRn, such as through use of an anti-FcRn antibody, has been shown to reduce levels of pathogenic IgG antibodies. ***Completed clinical trials of Immunovant and other anti-FcRn antibodies in IgG-mediated autoimmune diseases have generated promising results, suggesting that FcRn is a therapeutically important pharmacologic target to reduce levels of these disease-causing IgG antibodies***.
>
> ***In several nonclinical studies and a multi-part Phase 1 clinical trial in healthy volunteers, intravenous and subcutaneous delivery of IMVT-1401 demonstrated dose-dependent IgG antibody reductions and was observed to be well tolerated***. In the highest dose cohort from the multiple-ascending dose portion of the Phase 1 clinical trial, four weekly subcutaneous administrations of 680 mg resulted in a mean maximum reduction of serum IgG levels of 78%, with a standard deviation of 2%. ***IMVT-1401 was generally well-tolerated in this study, and the majority of adverse events, or AEs, reported were mild or moderate.*** Injection site reactions were similar between IMVT-1401 and placebo arms.
>
> * * *
>
> We are developing IMVT-1401 as a fixed-dose subcutaneous injection, with an initial focus on the treatment of MG, TED and WAIHA. In addition, we intend to announce three new indications for IMVT-1401 over the next 12 months.

(Emphasis added).

99. The statements referenced above in ¶98 were each inaccurate statements of material fact when made because of the reasons set forth in ¶94 above. The statements were misleading because they were contrasting the safety of IMVT-1401 with competing solutions but failed to disclose that there was an anticipated risk in IMVT-1401 of heart disease and elevated cholesterol levels, and by subsequent reasoning an increased long-term risk of cardiovascular disease, and that Immunovant was not even testing for that risk. The statement, "Completed clinical trials of Immunovant and other anti-FcRn antibodies in IgG-mediated autoimmune diseases have generated promising results" was misleading because Immunovant was not in position to represent that clinical trial results of IMVT-1401 were "promising" until it tested for its impact on cholesterol levels. The statement that "several nonclinical studies and a multi-part Phase 1 clinical trial" was "observed to be well tolerated" was untrue because the animal studies revealed substantial increases in cholesterol, and it was unknown whether the "Phase 1 clinical trial" was "well tolerated" because Immunovant failed to test cholesterol levels. The statements about Immunovant's intention "to announce three new indications for IMVT-1401 over the next 12 months" was materially misleading because it gave the impression of widespread adoption of IMVT-1401 in a short time frame even though the undisclosed safety issues of substantially elevated LDL and cholesterol levels, if publicly disclosed, threatened to delay and/or derail the estimated schedule for FDA approval of IMVT-1401.

100. The Sept. 2020 Offering Documents stressed the large size of the target markets for IMVT-1401 and that Immunovant would be able to move quickly during the clinical trial process to get regulatory approval, which would enable the Company to generate revenues, stating, in pertinent part, as follows:

> Our goal is to become a leading biopharmaceutical company in the development and commercialization of innovative therapies for autoimmune diseases with significant unmet need. To execute our strategy, we plan to:

- Maximize the probability of success of IMVT-1401. We plan to leverage IMVT-1401's differentiated profile in target indications where the anti-FcRn mechanism has already established clinical proof-of-concept. We intend to identify and target a variety of IgG-mediated autoimmune indications based on the following factors:

  • Inadequacy of the standard of care;

  • Disease severity that warrants novel therapies;

  • ***Ability to rapidly establish proof-of-concept through comparatively short duration clinical trials*** using validated clinical endpoints; and

  • Ability to ***rapidly initiate pivotal trial programs and potentially receive regulatory approval***.

* * *

The prevalence of certain IgG-mediated autoimmune diseases are set forth in the following table:

Indication	Estimated Prevalence (2019) U.S.	Europe*
Myasthenia Gravis	66,000	104,000
Warm Autoimmune Hemolytic Anemia	42,000	67,000
Thyroid Eye Disease	33,000	52,000
Idiopathic Thrombocytopenic Purpura	31,000	50,000
Pemphigus Vulgaris	28,000	45,000
Chronic Inflammatory Demyelinating Polyneuropathy	16,000	25,000
Bullous Pemphigoid	8,000	13,000
Neuromyelitis Optica	7,000	12,000
Pemphigus Foliaceus	7,000	11,000
Guillain-Barré Syndrome	3,000	5,000
PLA2R+ Membranous Nephropathy	2,000	4,000
Total	243,000	388,000

* Europe includes all E.U. countries, the U.K. and Switzerland

(Emphasis added).

101. The statements referenced above in ¶100 were each inaccurate statements of material fact when made because of the reasons set forth in ¶94 above. The Sept. 2020 Offering Documents highlighted the success and safety results of its preclinical and clinical tests of IMVT-1401 but failed to disclose that there was an anticipated risk that cholesterol levels would increase in patients and that Immunovant had not even tested the cholesterol levels in subjects during clinical trials.

102. The Sept. 2020 Offering Documents described Immunovant and its development and testing of IMVT-1401, stating, in pertinent part, as follows:

> ***In a Phase 1 clinical trial***, IMVT-1401 has demonstrated dose-dependent reductions in serum levels of IgG antibodies and was ***well-tolerated*** following subcutaneous and intravenous administration to healthy volunteers. In addition, completed clinical trials of other anti-FcRn antibodies have produced positive proof-of-concept activity in multiple IgG-mediated autoimmune diseases. We believe that these ***data support FcRn as a viable pharmacologic target with the potential to address multiple IgG-mediated autoimmune diseases.*** We intend to develop IMVT-1401 as a fixed-dose, self-administered subcutaneous injection on a convenient weekly, or less frequent, dosing schedule.

(Emphasis added).

103. The statements referenced above in ¶102 were each inaccurate statements of material fact when made because of the reasons set forth in ¶94 above.

104. The Sept. 2020 Offering Documents represented positive facts about prior and ongoing trials of IMVT-1401 but failed to disclose the risk of increased cholesterol or that the Company hadn't even tested for cholesterol in completed trials, stating, in pertinent part, as follows:

> **Phase 1 Clinical Trials of IMVT-1401 in Healthy Volunteers**
>
> We have completed a multi-part, placebo-controlled Phase 1 clinical trial involving 99 healthy volunteers in Australia and Canada, administering IMVT-1401 both as an intravenous infusion and as a subcutaneous injection. In this trial, 77 subjects received at least one dose of IMVT-1401 and 22 subjects received placebo.
>
> * * *
>
> ***The IgG reductions we observed in this multi-part, placebo-controlled Phase 1 clinical trial support the continued development of IMVT-1401***, however, this trial did not include pre-specified endpoints for IgG reduction, and we cannot be certain that similar IgG reductions will be observed in any future clinical trials.
>
> *Safety Data*
>
> ***In our multi-part, placebo-controlled Phase 1 clinical trial, IMVT-1401 has been observed to be well-tolerated with no Grade 3 or Grade 4 treatment emergent AEs and no discontinuations due to AEs. The most commonly reported AE has been mild erythema and swelling at the injection site, which typically resolved within hours and had a similar incidence between subjects receiving IMVT-1401 and placebo.*** These reactions at the injection site were not considered dose-related and did not increase with multiple administrations of IMVT-1401 in the multiple-dose cohorts. ***To date, two serious AEs have been reported, both of which have been***

> ***assessed as unrelated to IMVT-1401 by the study investigator. There have been no treatment-related serious AEs reported***.
>
> * * *
>
> ***Dose-dependent and reversible albumin reductions were observed in the single-ascending and multiple-ascending dose cohorts***. In the 680 mg multiple-ascending dose cohort, most subjects reached nadir before administration of the final dose. Mean reduction in albumin levels at day 28 were 20% in the 340 mg multiple-dose cohort, and 31% in the 680 mg multiple-dose cohort. For subjects in the 340 mg and 680 mg cohorts, the mean albumin levels at day 28 were 37.5 g/L and 32.4 g/L, respectively (normal range 36-51 g/L). ***These reductions were not associated with any AEs or clinical symptoms and did not lead to any study discontinuations***.

(Emphasis added).

105. The statements referenced above in ¶104 were each inaccurate statements of material fact when made because of the reasons set forth in ¶94 above. The statement "observed to be well-tolerated with no Grade 3 or Grade 4 treatment emergent AEs and no discontinuations due to AEs" was misleading because Immunovant had observed substantially elevated cholesterol levels in the animal studies, and it was an anticipated risk that there would also be substantially elevated levels in humans. The statements about a lack of AEs were also misleading because it gave the impression that there were not elevated cholesterol levels even though Immunovant was not testing for cholesterol.

106. The Sept. 2020 Offering Documents contained a table of the "Most Common Adverse Events Reported in Phase 1 Clinical Trial of IMVT-1401" but the table failed to properly disclose safety concerns related to cholesterol.

107. The Sept. 2020 Offering Documents discussed other pre-clinical and clinical trials by the Company of IMVT-1401, stating, in pertinent part, as follows:

> ***Nonclinical Studies of IMVT-1401***
>
> Cynomolgus monkeys were selected as the primary species for nonclinical testing, given the high degree of sequence homology to human FcRn and IMVT-1401's strong binding affinity for monkey FcRn. Our partner, HanAll, completed five

> nonclinical studies of IMVT-1401 (referred as HL161BKN for the purposes of these studies) in cynomolgus monkeys.
>
> * * *
>
> Importantly from the 26-week toxicity study, based on the overall toxicity profile following 26 weeks of SC injections (200 mg/kg/week), the No-Observed-Adverse-Effect-Level (NOAEL) of IMVT-1401 following SC injection was concluded to be 100 mg/kg/dose or 200 mg/kg/week; we estimate that this represents an approximate 3-fold safety margin (100 mg/kg/dose) when compared to the planned clinical dose of 680 mg/dose taking into account allometric corrections between monkeys and humans. Moreover, the estimated safety margin is increased to approximately 6-fold when considering IMVT-1401 was administered twice per week at 200 mg/kg/week. Overall, in these nonclinical studies, there was a robust PK/TK and PD correlation in cynomolgus monkeys after removing the confounding element of ADA. The immunogenicity response to human proteins generated in nonclinical species is generally not predictive of that in the human. ***Nevertheless, subjects in clinical trials with IMVT-1401 will be carefully monitored for any AEs, including those related to immunogenicity.***

(Emphasis added).

108. The statements referenced above in ¶¶106-107 were each inaccurate statements of material fact when made because Immunovant's animal studies revealed substantial increases in cholesterol for animals taking IMVT-1401. Additionally, it was not true that "subjects in clinical trials with IMVT-1401 will be carefully monitored for any AEs." Rather, Immunovant was not carefully monitoring for the AE of elevated total cholesterol and LDL levels.

109. The Sept. 2020 Offering Documents discussed the ASCEND clinical trials of IMVT-1401, stating, in pertinent part, as follows:

> ***ASCEND MG Trial***
>
> In August 2019, we initiated dosing in our ASCEND MG clinical trial. The ASCEND MG trial is a multi-center, randomized, placebo-controlled Phase 2a clinical trial designed to evaluate the safety, tolerability, pharmacodynamics, and efficacy of IMVT-1401 in patients with moderate-to-severe MG, as defined by MGFA Class II through IVa, and QMG scores greater than or equal to 12 … The primary endpoints of this trial are assessment of the safety and tolerability of IMVT-1401 and measurement of the changes from baseline in levels of total IgG subclasses and anti-AChR IgG…***Consistent with previously reported Phase 1 results, IMVT-***

1401 was observed to be well-tolerated with no SAEs reported, no withdrawals due to AEs, and no imbalance in headaches.

* * *

ASCEND GO-1 Trial

In May 2019, we initiated dosing in our ASCEND GO-1 trial, an open label single-arm Phase 2a clinical trial of IMVT-1401 in Canada in patients with TED. We announced initial results from this trial in March 2020. Patients recruited for this trial have moderate-to-severe active TED with confirmed autoantibodies to TSHR. A total of seven patients were dosed weekly with subcutaneous injections for six weeks. The trial utilized an induction and maintenance strategy, using only subcutaneous injections. Patients received a 680 mg dose for the first two administrations of study followed by a 340 mg dose for the final four administrations. The primary endpoints of this trial are safety and tolerability of IMVT-1401 over the six-week treatment period, as well as the change from baseline in levels of anti-TSHR antibodies, total IgG antibodies and IgG antibodies by subclasses…***The safety and tolerability profile observed was consistent with the prior Phase 1 trial of IMVT-1401 in 99 healthy volunteers. Mean albumin reduction from baseline to end of treatment was 24%. All AEs were mild or moderate and there were no headaches reported.***

* * *

ASCEND WAIHA Trial

In November 2019, we submitted our IND to the FDA for WAIHA and, in December 2019, our IND was cleared for Phase 2 trial initiation. The ASCEND WAIHA trial will explore the potential of IMVT-1401 to increase hemoglobin levels and assess the safety and tolerability of IMVT-1401 in this population. Patients in this trial will be treated with one of two doses of IMVT-1401 (680 mg or 340 mg) administered weekly by subcutaneous injection for 12 weeks. The primary endpoint of this trial is the proportion of responders, defined as patients achieving a hemoglobin level of at least 10 g/dL and at least a 2 g/dL increase from baseline. Secondary endpoints include change from baseline in other hematologic and chemistry parameters, time to response, patient reported outcome measures, total IgG antibodies and IgG antibodies by subclasses. We plan to report initial results from the high-dose cohort of this Phase 2a trial of IMVT-1401 in patients with WAIHA in the first quarter of calendar year 2021.

(Emphasis added).

110. The statements referenced above in ¶109 were each inaccurate statements of material fact when made because of the reasons set forth in ¶94 above. The statements, "[t]he ASCEND MG trial assesses safety and efficacy of IMVT-1401" and "IMVT-1401 was observed to be well-tolerated with no SAEs reported" was misleading because Immunovant failed to test cholesterol

levels. The statements, "[t]he safety and tolerability profile observed was consistent with the prior Phase 1 trial of IMVT-1401" and "[a]ll AEs were mild or moderate" were misleading because Immunovant failed to test for the anticipated risk of elevated cholesterol levels and Immunovant, therefore, could not have been aware of "all AEs" that should have been tested under Clinical Good Practices.

111. The Sept. 2020 Offering Documents discussed the ASCEND GO-2 Phase 2b trial, stating, in pertinent part, as follows:

> **ASCEND GO-2 Trial**
>
> In October 2019, we initiated dosing in our ASCEND GO-2 trial, a randomized, masked, placebo-controlled Phase 2b clinical trial in 77 patients with moderate-to-severe active TED with confirmed autoantibodies to TSHR. The ASCEND GO-2 trial explores the potential of IMVT-1401 to improve proptosis and ***assesses the safety and tolerability of IMVT-1401 in this population.*** Patients in this trial will be treated with one of three doses of IMVT-1401 (680 mg, 340 mg or 255 mg) or placebo administered weekly by subcutaneous injection for 12 weeks. The primary endpoints of this trial are the proptosis responder rate measured at week 13, defined as the percentage of patients with a greater than or equal to 2 mm reduction in proptosis in the study eye without deterioration in the fellow eye, and safety and tolerability… We currently remain on track to report initial results from our ASCEND GO-2 trial in the first half of calendar year 2021.

(Emphasis added).

112. The statement referenced above in ¶111 was misleading because they failed to disclose that this was the first clinical trial in which Immunovant tested for cholesterol levels.

113. The Sept. 2020 Offering Documents discussed the near-term timetable for progress on its Phase 2 clinical trials and starting of Phase 3 trials, stating, in pertinent part, as follows:

> We anticipate initiating our Phase 3 clinical trial of IMVT-1401 in patients with MG in the first half of calendar year 2021. We currently remain on track to report initial results from our ASCEND GO-2 trial in the first half of calendar year 2021. We plan to report initial results from the high dose cohort of our Phase 2a trial of IMVT-1401 in patients with WAIHA in the first quarter of calendar year 2021.

114. The statement referenced above in ¶113 was misleading because it provided a positive and quick timeframe for the progress on the clinical trials. The undisclosed safety issues of substantially elevated LDL and cholesterol levels, if publicly disclosed, threatened to delay and/or derail IMVT-1401's prospects for commercial viability and profitability.

The September 2020 Offering Documents Omitted Known Trends, Events and Uncertainties that Were Impacting, and Would Impact, the Company's Financial Results

115. Pursuant to Item 10 of Form S-11, registrants are required to provide the information required by Item 303 of Regulation S-K [17 C.F.R. §229.303], including any known trends, events or uncertainties that have caused or are reasonably likely to cause the registrant's financial information not to be indicative of future operating results. This includes descriptions and amounts of matters that have had a material impact on reported operations, as well as matters that are reasonably likely based on management's assessment to have a material impact on future operations.

116. The increase in cholesterol levels in animals, the fact that it was an anticipated risk that IMVT-1401 would increase cholesterol levels in patients, that none of the completed clinical studies had yet tested cholesterol levels, and that the ASCEND GO-2 Phase 2b trial was the first clinical trial to test for cholesterol levels, were known events and uncertainties that were having and were reasonably likely to have an impact on the Company's continuing operations and therefore were required to be disclosed in the Sept. 2020 Offering Documents, but were not.

117. In 1989, the SEC issued an interpretive release on Item 303 and the disclosure required under the regulation. *See* Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A"), SEC Release No. 6835, 1989 WL 1092885, at *1 (May 18, 1989) (hereinafter referred to as "1989 Interpretive Release"). In the 1989 Interpretive Release, the SEC stated that:

> Required disclosure is based on *currently known trends, events and uncertainties that are reasonably expected to have material effects*, such as: A reduction in the

> registrant's product prices; erosion in the registrant's market share; changes in insurance coverage; or the likely non-renewal of a material contract. . . . A disclosure duty exists where a trend, demand, commitment, event or uncertainty is both presently known to management and reasonably likely to have material effects on the registrant's financial condition or results of operation.

Id. at *4.

118. Furthermore, the 1989 Interpretive Release provided the following test to determine if disclosure under Item 303(a) is required:

> Where a trend, demand, commitment, event or uncertainty is known, management must make two assessments:
>
> (1) Is the known trend, demand, commitment, event or uncertainty likely to come to fruition? If management determines that it is not reasonably likely to occur, no disclosure is required.
>
> (2) If management cannot make that determination, it must evaluate objectively the consequences of the known trend, demand, commitment, event or uncertainty, on the assumption that it will come to fruition. Disclosure is then required unless management determines that a material effect on the registrant's financial condition or results of operations is not reasonably likely to occur.

Id. at *6.

The September 2020 Offering Documents Omitted to Include Significant Factors that Made the Offering Risky

119. Pursuant to Item 3 of Form S-11, the Sept. 2020 Offering Documents were required to furnish the information pursuant to Item 503 of Regulation S-K [17 C.F.R. §229.303], including, among other things, a "discussion of the most significant factors that make the offering risky or speculative," including the following:

(a) IMVT-1401 was less safe than the Company had led investors to believe;

(b) There was an anticipated risk that IMVT-1401 would substantially increase LDL and cholesterol levels because, among other reasons;

(c) Immunovant's animal studies for IMVT-1401 revealed a substantial increase in cholesterol for animals that received IMVT-1401:

(i) IMVT-1401 was in a class of drug which lowered serum albumin levels, and medical journals and studies reported that low serum albumin levels increases LDL and cholesterol levels;

(d) Thyroid conditions which were indications for IMVT-1401, such as Grave's Ophthalmopathy and myasthenia gravis, are known to reduce cholesterol, so if IMVT-1401 is successful in treating the underlying thyroid condition, it should be expected that cholesterol would increase;

(e) Immunovant failed to test for the anticipated risks and adverse events of elevated LDL or cholesterol levels in any of its phase 1 or 2 clinical trials conducted prior to its ASCEND GO-2 Phase IIb trial which was halted, as announced on February 2, 2021;

(f) Immunovant was required to report to the FDA that its animal studies showed a substantial increase in cholesterol levels for animals taking IMVT-1401. Upon information and belief, Immunovant failed to inform the FDA of the substantial increases in cholesterol experienced by animals; and

(g) The undisclosed safety issues of substantially elevated LDL and cholesterol levels, if publicly disclosed, threatened to delay and/or derail IMVT-1401's prospects for commercial viability and profitability.

Any Purported Risk Warnings in the September 2020 Offering Documents Were Inadequate or Materially False and Misleading

120. Even though the Sept. 2020 Offering Documents contained purported risk warnings or warnings that certain statements may be forward-looking, they did not adequately warn investors about the untrue facts, misrepresentations and omissions alleged herein. These risk warnings: (i) were false or misleading as a matter of current or historical fact; and/or (ii) were not meaningful

because, among other things, they were vague, boilerplate and did not adequately warn of the true risks of investing in Immunovant.

121. The Sept. 2020 Offering Documents purported to warn about delays in clinical trials, and stated, in pertinent part, as follows:

> ***We are reliant on third parties to conduct, supervise and monitor our clinical trials, and if those third parties perform in an unsatisfactory manner or fail to comply with applicable requirements, it may harm our business.***
>
> We currently do not have the ability to independently conduct nonclinical studies that comply with Good Laboratory Practice, or GLP, requirements. We also do not currently have the ability to independently conduct any clinical trials. We rely exclusively on CROs and clinical trial sites, which need to comply with GCP, to ensure the proper and timely conduct of our clinical trials, and we have limited influence over their actual performance.

122. The statements referenced above in ¶121 were false or misleading as a matter of current or historical fact and/or were not meaningful because the Sept. 2020 Offering Documents should have warned that the Company would encounter problems causing it to abandon or repeat clinical trials of IMVT-1401 because the Company knew IMVT-1401 was unsafe.

123. The Sept. 2020 Offering Documents purported to warn about safety or adverse events delaying clinical trials, and stated, in pertinent part, as follows:

> Failures can occur at any stage of clinical trials, and we could encounter problems that cause us to abandon or repeat clinical trials. In addition, results from clinical trials may require further evaluation, delaying the next stage of clinical development or submission of a BLA. Further, product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through nonclinical studies and initial clinical trials, and such product candidates may exhibit negative safety signals in later stage clinical trials that they did not exhibit in nonclinical or earlier-stage clinical trials…
>
> The commencement and completion of clinical trials may be delayed by several factors, including: …
>
> - unforeseen safety issues, or subjects experiencing severe or unexpected adverse events, or AEs;

* * *

> ***Our product candidate may cause adverse events or have other properties that could delay or prevent their regulatory approval, cause us to suspend or discontinue clinical trials, abandon further development or limit the scope of any approved label or market acceptance***.
>
> Adverse events associated with our product candidate in our clinical trials could cause us, other reviewing entities, clinical trial sites or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval.

124. The statements referenced above in ¶123 were false or misleading as a matter of current or historical fact and/or were not meaningful because the Sept. 2020 Offering Documents should have warned that safety issues and/or adverse events occurring in IMVT-1401 clinical trials were extremely likely because the Company knew that IMVT-1401 had safety issues. Defendants should have warned that IMVT-1401 could cause changes in cholesterol levels and therefore it was highly probable – if not certain – that clinical trials would be halted and/or could have impacted the FDA's review and approval of the product.

125. The Sept. 2020 Offering Documents purported to warn that the Company evaluated IMVT-1401 in nonclinical studies and early-stage clinical trials, and stated, in pertinent part, as follows:

> ***The results of our nonclinical and clinical trials may not support our proposed claims for our product candidate, or regulatory approval on a timely basis or at all, and the results of earlier studies and trials may not be predictive of future trial results***.
>
> * * *
>
> ***We are at an early stage in our development efforts for IMVT-1401 and we may not be able to successfully develop and commercialize our product candidate on a timely basis or at all.***
>
> We have not yet succeeded and may never succeed in demonstrating efficacy and safety for IMVT-1401 in pivotal clinical trials or in obtaining marketing approval thereafter. For example, although we and our licensing partner have evaluated IMVT-1401 nonclinical studies and in early-stage clinical trials, we have not yet advanced IMVT-1401 into a large-scale, pivotal clinical trial for any indication. Positive results from our early-stage clinical trials are not necessarily predictive of the results of our planned clinical trials of IMVT-1401.

126. The statements referenced above in ¶125 were false or misleading as a matter of current or historical fact and/or were not meaningful because the Sept. 2020 Offering Documents should have warned that nonclinical and early-stage clinical trials of IMVT-1401 showed a dangerous increase in cholesterol levels and therefore the Company should have warned that it would not succeed in demonstrating safety for IMVT-1401. Further, this warning does not disclose that nonclinical studies presented an increase in cholesterol levels and so the results of said nonclinical trials could not support the Company's proposed claims for its product candidate.

127. The Sept. 2020 Offering Documents purported to warn that safety issues in IMVT-1401 would have a material adverse effect on business, and stated, in pertinent part, as follows:

> ***Our business is heavily dependent on the successful development, regulatory approval and commercialization of our sole product candidate, IMVT-1401.***
>
> * * *
>
> In addition, ***if our product candidate encounters safety or efficacy problems,*** developmental delays, regulatory issues, supply issues, or other problems in one of our target indications, ***our development plans for our product candidate could be significantly harmed in other indications, which would have a material adverse effect on our business.***

128. The statements referenced above in ¶127 were false or misleading as a matter of current or historical fact and/or were not meaningful because the Sept. 2020 Offering Documents should have warned that IMVT-1401, the Company's only drug candidate, did in fact have safety issues.

The Company's Stock Declines

129. On February 2, 2021, Immunovant issued a press release "announc[ing] a voluntary pause in clinical dosing of IMVT-1401." Specifically, that press release stated, in relevant part:

> The Company has become aware of a physiological signal consisting of elevated total cholesterol and LDL levels in IMVT-1401-treated patients in ASCEND GO-2, a Phase 2b trial in Thyroid Eye Disease (TED). Cholesterol levels were not measured in prior clinical trials of IMVT-1401 in Myasthenia Gravis (MG) and in healthy

> subjects. Out of an abundance of caution, the Company has decided to voluntarily pause dosing in ongoing clinical studies in both TED and in Warm Autoimmune Hemolytic Anemia, in order to inform patients, investigators, and regulators as well as to modify the monitoring program.
>
> ASCEND GO-2 is a randomized, placebo-controlled trial in TED evaluating different doses, each given weekly for 12 weeks. In this study, cholesterol parameters are assessed at baseline, at twelve weeks, and at week 20 following eight weeks off drug. Based on preliminary, unblinded data from about 40 patients through week 12, mean LDL cholesterol at week 12 was increased by approximately 65% in the 680mg dose group, by approximately 40% in the 340mg dose group, and did not increase in the control group. Average HDL and triglyceride levels increased to a much lesser degree. For context, commercially available statins report a reduction in LDL cholesterol between 27-60%. At the twenty-week timepoint, average LDL levels had declined to baseline or lower in the 680mg dose group, in the 340mg dose group, and in the control group. No serious cardiovascular events have been reported to date in IMVT-1401 clinical trials.
>
> Harbour BioMed, the license holder for 1401 in Greater China, has informed Immunovant that based on their preliminary review of blinded data in their ongoing clinical studies in Chinese patients with MG and Idiopathic Thrombocytopenic Purpura, similar increases in cholesterol have not been observed. The Company is not aware whether trials involving other anti-FcRn agents in development have performed detailed assessments of lipid parameters.
>
> The Company will work closely with regulators and scientific experts to characterize the detailed profile of these lipid changes and to understand the mechanism of these changes across indications. After discussion and agreement with regulators regarding protocol modifications, the Company intends to continue to pursue development of IMVT-1401.
>
> Immunovant will host a conference call on Tuesday, February 2 at 8:00am EST. Following prepared remarks, the call will include a live question-and-answer session for the investment community.

130. That same day, Immunovant hosted a Special Call for analysts and investors to discuss the Company's press release and the halting of the IMVT-1401 studies (the "2/2/21 Conf Call"). During the 2/2/21 Conf Call, Defendant Salzmann discussed the voluntary pause in clinical dosing of IMVT-1401, stating, in pertinent part, as follows:

> Immunovant is voluntarily pausing dosing in our clinical trials of IMVT-1401. We just recently became aware of a physiological signal consisting of elevated total cholesterol and LDL in IMVT-1401-treated patients in our thyroid eye disease Phase IIb trial. We decided to pause dosing in our active clinical trials so that we could

> carefully review the data, so that we could notify regulators and investigators and so that we could make modifications to the patient consent form as well as to the lipid monitoring and management parameters in our program.

131. During the 2/2/21 Conf Call, Defendant Salzmann responded to a question about the declines in albumin, stating, in pertinent part, as follows:

> So for the 680-milligram dose in the Phase I trial and in the myasthenia gravis trial, we saw reductions in albumin of 25% to 30%. That's the average for the group. And in the 340-milligram dosage arm in the Phase I trial as well as in the myasthenia trial, we saw reductions in the 15%-20%-range group average mean change from baseline.

132. During the 2/2/21 Conf Call, Defendant Salzmann acknowledged that an increase in cholesterol could be associated with the treatment of the underlying TED condition, stating, in pertinent part, as follows:

> ***Samuel Evan Slutsky*** *- LifeSci Capital, LLC, Research Division - Senior Research Analyst*
>
> Okay. And then, I guess, in terms of TED specifically. Since they have hyperthyroidism, which could be associated, I guess, with LDL, is it possible that the increases could be due to normalizing of thyroid function? Maybe it's overshooting. Or kind of what's your take on that since it's kind of specific to TED, that hyperthyroid is an aspect?
>
> ***Peter Salzmann*** *- Immunovant, Inc. - CEO & Director*
>
> Yes, I think that's a plausible hypothesis and one we're definitely going to look into. The patients are not hyperthyroid at enrollment. So they do have obviously the presence of thyroid-stimulating auto antibodies. And then their hyperthyroidism is controlled in one way or another, and there's a requirement that they'd be relatively euthyroid. They can't be more than 50% hyper or hypothyroid, based on their TSH and T3 levels. So there's some variability when they enter. And as I mentioned earlier, we did collect TSH and T3 and T4 levels, and so we have a chance and opportunity to look for correlations there, which we'll be doing.

133. On the 2/2/21 Conf Call, Defendant Salzmann acknowledged the importance of the cholesterol readings to the IMVT-1401 clinical studies, stating, in pertinent part, as follows:

> So this is the excursions in cholesterol was something that we just recently became aware of in our data set. And when we became aware of it, we dug into it and quickly and then made a decision to unblind the data set and presenting the information that we found to regulators and investigators today and as well as investors.

134. Following the Company's February 2, 2021 announcement, the price of Immunovant stock collapsed from a closing price of $43.30 per share on February 1, 2021 to a closing price of $25.08 per share on February 2, 2021, a one day decline of $18.22 per share, or 42.08%, on extremely heavy trading volume of 11.76 million shares. Immunovant stock continued to decline for the next several days, and by February 16, 2021 Immunovant stock traded at $16.17 per share.

135. An article titled *Stock Alert: Immunovant Falls 43% After Voluntary Pause in IMVT-1401 Clinical Dosing* by NASDAQ published on February 2, 2021, stated, in pertinent part, as follows:

> (RTTNews) - Shares of Immunovant, Inc. (IMVT), a clinical-stage biopharmaceutical company, are tumbling 43 percent or $18.62 in Tuesday's morning trade at $24.68. Tuesday, Immunovant announced a voluntary pause of dosing in its ongoing clinical trials for IMVT-1401. The company said it has become aware of a physiological signal consisting of elevated total cholesterol and LDL levels in IMVT-1401-treated patients in ASCEND GO-2, a Phase 2b trial in Thyroid Eye Disease or TED. Cholesterol levels were not measured in prior clinical trials of IMVT-1401 in Myasthenia Gravis (MG) and in healthy subjects.

136. An article titled *Immunovant stock loses half its value after pausing dosing in trial of thyroid eye disease treatment* by Market Watch published on February 2, 2021, stated, in pertinent part, as follows:

> Shares of Immunovant…plunged 49.8% to pace all premarket losers Tuesday, after the biopharmaceutical company said it has paused dosing in its phase 2b trial for IMVT-1401, a treatment for thyroid eye disease (TED). The company said it voluntarily decided to pause dosing, "out of an abundance of caution," after it became aware of a physiological signal consisting of elevated total cholesterol, as cholesterol levels were not measured in prior trials. The company said it is pausing dosing in order to inform patients, investigators and regulators, as well as to modify the monitoring program.

137. An article titled *Why Immunovant Stock Dropped Today* by The Motley Fool published on February 2, 2021, stated, in pertinent part, as follows:

> Shares of Immunovant...were down by 43.2% as of 2:57 p.m. EST on Tuesday, after plunging by as much as 48% earlier in the day. The losses came after Immunovant announced an update regarding one of its ongoing clinical trials.

* * *

> The market doesn't like uncertainty, and while we don't know for sure whether the higher LDL observed in patients taking IMVT-1401 after 12 weeks was due to the experimental medicine, today's news was enough to scare off investors. ***And considering IMVT-1401 is Immunovant's only pipeline candidate at the moment (the company has no products on the market), staying far away from this healthcare stock seems like the right move.***

138. An analyst report on the Company by UBS dated February 5, 2021, stated, in pertinent part, as follows:

> **LDL issue likely TED specific but sentiment damaged - value here for the patient**
>
> Following IMVT's update re raised LDL levels in IMVT-1401-treated patients in the TED trial, we are lowering our PT to $33 (from $67). Our work-to-date (see inside) indicates this issue is likely specific to TED, supported by the fact that Harbour BioMed's (holder of '1401 license in China) review of blinded data across MG and ITP studies did not observe similar findings. However, it remains that a very real and meaningful increase in LDL levels (40-65%) was observed in the TED study and that it will take some time before sufficient analyses can be done to irrefutably answer the question whether this is TED specific. For now, we expect a significant overhang to remain given investors' probability of success, penetration, launch timing and strategic interest assumptions are all negatively impacted. Prior to this update, IMVT stock had been under pressure, likely driven by de-risking ahead of the hard-to-handicap WAIHA readout - we expect this dynamic to remain. Our updated PT still supports a Buy rating but we acknowledge the stock could still remain pressured in the near-term and that downside risk remains.

139. An analyst report on the Company by H.C. Wainwright & Co. dated February 17, 2021, stated, in pertinent part, as follows:

> [M]anagement acknowledged that this effect may not simply be limited to TED and could be an undesirable side effect that Immunovant may have to manage commercially. If the lipid elevating effects are seen in MG or other indications, they could potentially be managed with statins, but would diminish the appeal of IMVT-1401 compared to argenx's (ARGX, Neutral) efgartigimod, that notably did not cause a cholesterol elevation upon treatment.

140. In connection with the halting of the IMVT-1401 studies and looking into the issue, Immunovant reviewed various materials and information at the Company, including the results of the animal studies. In connection with that investigation, FE reviewed the reports for the

IMVT-1401 animal studies. According to FE, the cholesterol for the animals were tested in the IMVT-1401 animal studies and the results of those studies showed that animals which were administered IMVT-1401 had developed substantially elevated LDL and cholesterol levels compared with those animals in the control group which did not take IMVT-1401. FE recalled that the investigation and review of the animal studies took place in early January 2021. According to FE, the written animal study reports contained a summary of the findings and while the data and test results from the studies readily showed cholesterol levels of as much as 200 to 300 percent higher than the levels of animals which did not take IMVT-1401, the summary of findings did not reflect this increase. FE did not recall anyone at the Company contacting the third-party that conducted the animal studies to inquire about or discuss the summaries not reflecting the substantial increases in cholesterol levels based on the data.

141. On June 1, 2021, the Company announced its financial and operational results for the fourth quarter 2021 ("4Q21") and for the full year ended March 31, 2021 ("FY21") in a press release (the "6/1/21 Press Release"), which it filed with the SEC on Form 8-K, and provided an update about the Company's investigation in the cholesterol issues announced on February 2, 2021. The 6/1/21 Press Release stated, in pertinent part, as follows:

> In a program-wide review, the company observed increases in LDL in multiple studies that were consistent, dose-related, and appear to be driven by reductions in albumin levels. No relationship to levels of thyroid hormone was observed. The increases in LDL and reductions in albumin were reversible upon cessation of dosing, and no major adverse cardiovascular events have been reported to date.
>
> * * *
>
> As part of the company's data review, the Ph 2b TED study was unblinded and terminated prior to completion. While the trial showed clear biologic activity based on changes in IgG and pathologic autoantibodies, prematurely terminating the study resulted in inconclusive efficacy results. Forty-one subjects out of a planned seventy-seven reached the twelve-week primary endpoint. Efficacy data in this underpowered subset was more modest than the company had hoped and was not statistically significant on the primary endpoint.

142. The 6/1/21 Press Release attached a presentation which acknowledged that "Albumin and LDL are tightly linked." The conclusions reported by Immunovant on June 1, 2021 are consistent with the information existing prior to and during the Class Period as alleged above concerning a known effect of FcRn inhibition on serum albumin levels and, subsequently, on cholesterol levels.

143. Following the Company's June 1, 2021 announcements, the price of Immunovant stock fell from a closing price of $15.16 per share on Friday, May 28, 2021, to a closing price of $9.40 per share on June 1, 2021, a one day decline of $5.76 per share, or 38%, on extremely heavy trading volume of 16.91 million shares.

144. An analyst report on the Company by Guggenheim dated June 1, 2021, stated, in pertinent part, as follows:

> [T]he TED program, which was stopped after observed lipid changes, failed to produce robust efficacy in the Phase II…a path forward will require additional feedback from regulators/KOLs, and ***we think the potential is limited in this indication given the lack of robust efficacy and competition in the space***…Downgrading to Neutral and removing our PT based on the limited potential for IMVT-1401 given the competitive landscape (ARGX's efgartigimod, HZNP's Tepezza) ***and the observed lipid safety issues, which are likely to be an issue for all proposed indications.***

(Emphasis added).

145. An analyst report on the Company by Credit Suisse dated June 1, 2021, stated, in pertinent part, as follows:

> **Increases in LDL Levels Across Programs Put a Dent on Competitive Profile**. IMVT confirmed that increased LDL levels previously observed from the TED Ph2b (ASCENDGO-2) trial were in fact consistent and dose-related across multiple studies (believed to be driven by reductions in albumin), and not correlated with thyroid hormone levels. While IgG reductions in the ASCEND-GO-2 trial were robust at higher doses (340mg and 680mg), the increases in LDL and lower than expected efficacy (41 of planned 77 patients reached 12w endpoint) may confine IMVT-1401 to lower doses (255mg)—limiting the appeal in TED…While ultimately the LDL levels might be manageable, ***we think IMVT-1401 may struggle to differentiate favorably to other FcRn agents that have minimal impact to albumin levels***. As a

> result, we lower to TP to $12 to reflect the lower probability-of-success (PoS) in TED and the heightened uncertainty across other programs (lower PoS/peak sales).

(Emphasis added).

COUNT I

Violations of Section 11 of the Securities Act Against Immunovant, the Securities Act Individual Defendants, and the Underwriter Defendants

146. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

147. This Count is brought pursuant to Section 11 of the Securities Act, 15 U.S.C. §77k, and is asserted against Immunovant, the Underwriter Defendants, and the Securities Act Individual Defendants. Plaintiff does not claim for purposes of this Count that Defendants committed intentional or reckless misconduct or acted with scienter or fraudulent intent.

148. The Registration Statement for the September 2020 Offering was inaccurate and misleading, contained untrue statements of material facts, omitted facts necessary to make the statements made therein not misleading, and omitted to state material facts required to be stated therein.

149. Immunovant is the registrant for the September 2020 Offering. As issuer of the shares, Immunovant is strictly liable for the materially inaccurate statements contained in the Registration Statement and the Prospectus and the failure of the Registration Statement and Prospectus to be complete and accurate.

150. The Securities Act Individual Defendants each signed the Registration Statement either personally or through an Attorney-in-Fact and/or caused its issuance. The Securities Act Individual Defendants each had a duty to make a reasonable and diligent investigation of the truthfulness and accuracy of the statements contained in the Registration Statement. They had a duty to ensure that such statements were true and accurate, that there were no omissions of material fact

that would make the statements misleading and that the documents contained all facts required to be stated therein. In the exercise of reasonable care, the Securities Act Individual Defendants should have known of the material misstatements and omissions contained in the Registration Statement and also should have known of the omissions of material fact that were necessary to make the statements made therein not misleading. As such, the Securities Act Individual Defendants are liable to Plaintiff and the Class.

151. The Underwriter Defendants were each underwriters, as that term is used in Section 11(a)(5) of the Securities Act, with respect to the September 2020 Offering and the Company's securities were sold through the Registration Statement. The Underwriter Defendants were required to investigate with due diligence the representations contained therein to confirm that they did not contain materially misleading statements or omit material facts. None of the Underwriter Defendants made a reasonable investigation or possessed reasonable grounds for the belief that the statements described herein, which were contained in the Registration Statement and Prospectus, were true, were without omission of any material facts, and/or were not misleading.

152. By reasons of the conduct herein alleged, each Defendant violated Section 11 of the Securities Act.

153. Plaintiff and putative Class members acquired Immunovant common stock in the September 2020 Offering, and in reliance on the Registration Statement and without knowledge of the untruths and/or omissions alleged herein. Plaintiff and the Class sustained damages when the price of IMVT securities declined substantially subsequent to and due to Defendants' violations.

COUNT II

Violations of Section 12(a)(2) of the Securities Act Against Immunovant, the Securities Act Individual Defendants, and the Underwriter Defendants

154. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

155. This Count is brought pursuant to Section 12(a)(2) of the Securities Act, 15 U.S.C. §77l, on behalf of Plaintiff and the Class, against Immunovant, the Securities Act Individual Defendants, and the Underwriter Defendants (the "Count II Defendants"). Plaintiff does not claim for purposes of this Count that Defendants committed intentional or reckless misconduct or acted with scienter or fraudulent intent.

156. The Count II Defendants were sellers and offerors and/or solicitors of purchasers of the securities offered pursuant to the September 2020 Offering Prospectus. The Count II Defendants issued, caused to be issued, and/or signed the Registration Statement in connection with the September 2020 Offering. The Registration Statement contained a Prospectus which was used to induce investors, such as Plaintiff and the other members of the Class, to purchase Immunovant securities.

157. The September 2020 Offering Prospectus contained untrue statements of material fact, omitted to state other facts necessary to make the statements made not misleading, and omitted material facts required to be stated therein. The Securities Act Individual Defendants' actions of solicitation included participating in the preparation of the false and misleading Prospectus and in road shows to promote the September 2020 Offering. Immunovant and the Underwriter Defendants, acting through their employees, agents, and others, solicited such purchases for their personal financial gain through the preparation and dissemination of the Prospectus.

158. The Underwriter Defendants participated in the preparation and dissemination of the false and misleading Prospectus for their own financial benefit. But for their participation in the September 2020 Offering, including their solicitation as set forth herein, that offering could not and would not have been accomplished. Specifically, the Underwriter Defendants:

(a) made the decision to conduct the September 2020 Offering and do it at the price set forth in the offering documents. The Underwriter Defendants drafted, revised and/or approved the Prospectus. The Prospectus was calculated to create interest in Immunovant securities and was widely distributed by or on behalf of these Defendants for that purpose;

(b) finalized the Prospectus and caused it to become effective; and

(c) conceived and planned the September 2020 Offering and orchestrated all activities necessary to affect the sale of these securities to the investing public, by issuing securities, promoting the securities and supervising their distribution and ultimate sale to the investing public.

159. As set forth more specifically above, the Prospectus contained untrue statements of material fact and omitted to state material facts necessary in order to make the statements, in light of circumstances in which they were made, not misleading.

160. Plaintiff and the other Class members did not know, nor could they have known, of the untruths or omissions contained in the Prospectus.

161. The Count II Defendants were obligated to make a reasonable and diligent investigation of the statements contained in the Prospectus to ensure that such statements were true and that there was no omission of material fact required to be stated in order to make the statements contained therein not misleading. None of the Count II Defendants made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Prospectus were

accurate and complete in all material respects. Had they done so, these Defendants would have known of the material misstatements and omissions alleged herein.

162. By reason of the conduct alleged herein, the Count II Defendants violated Section 12(a)(2) of the Securities Act. Accordingly, Plaintiff and members of the Class who hold Immunovant common stock purchased in the Offering have the right to rescind and recover the consideration paid for their Immunovant common stock and hereby elect to rescind and tender their Immunovant common stock to the Defendants sued herein. Plaintiff and Class members who have sold their Immunovant common stock are entitled to rescissory damages.

COUNT III

Violations of Section 15 of the Securities Act
Against the Securities Act Individual Defendants and Roivant

163. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

164. This Count is brought pursuant to Section 15 of the Securities Act against the Securities Act Individual Defendants and Roivant. Plaintiff does not claim for purposes of this Count that Defendants committed intentional or reckless misconduct or acted with scienter or fraudulent intent.

165. Each of the Securities Act Individual Defendants and Roivant acted as controlling persons of Immunovant within the meaning of Section 15 of the Securities Act by virtue of their position as a director and/or senior officer of Immunovant and/or equity interest in control of the Company. By reason of their senior management positions, directorships at the Company, or stock ownership, as alleged above, the Securities Act Individual Defendants and Roivant, individually and acting pursuant to a common plan, had the power to influence and exercised the same to cause Immunovant to engage in the conduct complained of herein. By reason of such conduct, the

Securities Act Individual Defendants and Roivant are liable pursuant to Section 15 of the Securities Act.

166. Each of the Securities Act Individual Defendants and Roivant was a culpable participant in the violations of Sections 11 and 12(a)(2) of the Securities Act alleged in Counts I and II above, based on their having signed the Registration Statement and having otherwise participated in the process which allowed the September 2020 Offering to be successfully completed.

ADDITIONAL ALLEGATIONS IN SUPPORT OF CLAIMS UNDER THE EXCHANGE ACT

167. For purposes of the allegations under the Exchange Act set forth herein, the Individual Defendants refers to Defendants Salzmann, Connealy, and Wong and together with Immunovant and Roivant are the "Defendants."

Immunovant Failed to Test or Report on Cholesterol in Most of Its Clinical Trials to Postpone Potential Negative Consequences

168. Immunovant was required, but failed, to test for and report on cholesterol levels of participants in its IMVT-1401 Phase 1 and 2 trials. As alleged above in ¶82, elevated cholesterol levels were an anticipated risk of IMVT-1401. Additionally, Defendants knew, or recklessly disregarded, that the IMVT-1401 animal studies showed an increase in cholesterol levels for the tested animals so Immunovant should have designed all clinical studies to monitor cholesterol levels. Accordingly, Defendants knew, or recklessly disregarded, that IMVT-1401 would likely increase the cholesterol levels in patients taking the drug. Nevertheless, Immunovant, in violation of good clinical practices, failed to test for cholesterol in its completed clinical trials. Indeed, as admitted by Defendant Salzmann on February 2, 2021, the first time Immunovant tested for cholesterol levels in clinical trials was during the ASCEND GO-2 Phase 2b trial.

169. Failing to test for increase in cholesterol levels enabled Immunovant and other Defendants to delay having to potentially reveal that IMVT-1401 increased the cholesterol levels in

patients. Pushing back these cholesterol tests provided Defendants with time to raise hundreds of millions of dollars from investors and monetize their interest in IMVT-1401 before the potential risk of elevated cholesterol levels could derail the perceived viability of IMVT-1401. Upon information and belief, Defendants failed to test for cholesterol during the Phase 1 and Phase 2 tests of IMVT-1401 prior to the ASCEND GO-2 Phase 2b trial so that they could postpone having to potentially face clinical trial results showing increased cholesterol levels.

MATERIALLY FALSE AND MISLEADING STATEMENTS ISSUED DURING THE CLASS PERIOD

170. The Class Period starts on October 2, 2019. On that date, Immunovant and HSAC issued a press release (the "10/2/19 Press Release") titled "Immunovant to Merge with Health Sciences Acquisitions Corporation, Creating New Publicly Listed FcRn-Focused Company," announcing the merger between HSAC and Legacy Immunovant. The 10/2/19 Press Release discussed the terms of the merger, highlighted that a Phase 1 study had already been completed as a success, and that there were two ongoing Phase 2a trials, stating, in pertinent part, as follows:

- Immunovant is developing IMVT-1401, ***a fully human antibody to FcRn that delivered a mean IgG reduction of nearly 80% in a Phase 1 study*** of healthy volunteers receiving 4 weekly 680 mg subcutaneous injections
- Immunovant is expected to have more than $100 million at closing to fund development of IMVT-1401 into 2H 2021
- Top-line data from ongoing ***Phase 2a trial in Graves' ophthalmopathy expected by Q1 2020***
- Top-line data from ongoing ***Phase 2a trial in myasthenia gravis expected by Q2 2020***

* * *

Health Sciences Acquisitions Corporation ("HSAC," NASDAQ: HSAC), a special purpose acquisition company sponsored by RTW Investments, and Immunovant Sciences Ltd. ("Immunovant"), a clinical-stage biopharmaceutical company focused on enabling normal lives for patients with autoimmune diseases, today announced that they have entered into a definitive share exchange agreement ("SEA"). HSAC

> will acquire 100% of the issued and outstanding shares in Immunovant. Upon closing, the combined company will be called Immunovant, Inc.
>
> "We are thrilled to have the opportunity to partner with the team at Immunovant. ***We believe IMVT-1401 is a uniquely compelling asset within the FcRn drug class, which we expect will become a cornerstone therapy for treating many auto-antibody driven diseases," said Roderick T. Wong, M.D.,*** President, Chief Executive Officer and Chairman of HSAC and Managing Partner and Chief Investment Officer of RTW Investments.
>
> In addition to the merger described above, Immunovant also announced today that it completed a $35 million private bridge financing with RTW Investments, BVF Partners, and Roivant Sciences Ltd. ("Roivant"). The notes issued in this financing will convert into common shares of Immunovant immediately prior to the closing of the business combination.

(Emphasis added).

171. The statements referenced above in ¶170 were materially false and misleading when made because they misrepresented and failed to disclose the following adverse facts, which were known to Defendants or recklessly disregarded by them:

(a) IMVT-1401 was less safe than the Company had led investors to believe;

(b) There was an anticipated risk that IMVT-1401 would substantially increase LDL and cholesterol levels because, among other reasons:

(i) Immunovant's animal studies for IMVT-1401 revealed a substantial increase in cholesterol for animals that received IMVT-1401;

(ii) IMVT-1401 was in a drug class which lowered serum albumin levels, and medical journals and studies reported that low serum albumin levels increases LDL and cholesterol levels;

(iii) Due to the effect of albumin changes on cholesterol, Immunovant should have disclosed or at least tested cholesterol levels earlier than it did;

(iv) other companies researching the same class of drug apparently recognized this risk because they tested cholesterol levels; and

(v) thyroid conditions which were indications for IMVT-1401, such as Grave's Ophthalmopathy and myasthenia gravis, are known to reduce cholesterol, so if IMVT-1401 is successful in treating the underlying thyroid condition, it should be expected that cholesterol would increase.

(c) Immunovant failed to test for the anticipated risks and adverse events of elevated LDL or cholesterol levels in any of its phase 1 or 2 clinical trials conducted prior to its ASCEND GO-2 Phase 2b trial which was halted, as announced on February 2, 2021;

(d) Immunovant failed to follow FDA regulations and Good Clinical Practices in connection with IMVT-1401 because:

(i) it failed to perform ongoing surveillance of the adverse events and suspected adverse reactions of elevated LDL and total cholesterol levels; and

(ii) Immunovant was required to report to the FDA that its animal studies showed a substantial increase in cholesterol levels for animals taking IMVT-1401. Upon information and belief, Immunovant failed to inform the FDA of the substantial increases in cholesterol experienced by animals.

(e) The undisclosed safety issues of substantially elevated LDL and total cholesterol levels, if publicly disclosed, threatened to delay and/or derail IMVT-1401's prospects for commercial viability and profitability; and

(f) Immunovant's business, operations and financial condition was not as represented.

172. Defendant Wong's statement referenced in ¶170, "[w]e believe IMVT-1401 is a ***uniquely compelling*** asset within the FcRn drug class, which we expect will become a ***cornerstone therapy*** for treating many auto-antibody driven diseases[.]" was materially false and misleading

because IMVT-1401 was not "uniquely compelling" or would become a "cornerstone therapy" because it has an anticipated risk of substantially elevated cholesterol levels and Immunovant had not tested for cholesterol in clinical trials.

173. In the 10/2/19 Press Release, Defendant Salzmann discussed the Phase 1 and Phase 2 drug testing program for IMVT-1401, stating, in pertinent part, as follows:

> I am proud of the many milestones delivered by the Immunovant team this year, including completion of a ***comprehensive Phase 1 program*** demonstrating robust IgG reductions with simple subcutaneous injections and initiation of ***a broad Phase 2 program with both first-in-class and best-in-class potential*** in multiple diseases with high unmet patient need. We believe the potency of IMVT-1401 and the ability to administer IMVT-1401 as a simple subcutaneous injection represent important potentially differentiating features of this product candidate.

(Emphasis added).

174. The statement referenced above in ¶173 was materially false and misleading when made for the reasons set forth in ¶171 above. The statements "comprehensive Phase 1 program" and "broad Phase 2 program" with "best-in-class potential" were materially false and misleading when made because the Phase 1 and 2 programs failed to conform with Good Clinical Practices and failed to test for the anticipated risk of elevated cholesterol levels and its attendant long-term risk of cardiovascular disease.

175. The 10/2/19 Press Release stated, in pertinent part, as follows:

> In a Phase 1 study of healthy volunteers receiving 4 weekly subcutaneous injections, IMVT-1401 delivered a mean IgG reduction of 63% at a dose of 340 mg and a mean IgG reduction of 78% at a dose of 680 mg.
>
> * * *
>
> IMVT-1401 is currently being tested in a Phase 2a trial for Graves' ophthalmopathy (potentially a first-in-class anti-FcRn), with top-line data expected by Q1 2020, and in a Phase 2a trial for myasthenia gravis, with top-line data expected by Q2 2020.

176. The statements referenced above in ¶175 were materially false and misleading when made for the reasons set forth in ¶171 above. And because they failed to disclose that Immunovant's

clinical trials failed to conform with Good Clinical Practices and failed to test for the anticipated risk of elevated levels of cholesterol.

177. On October 11, 2019, Health Sciences Acquisitions Corporation and Immunovant Sciences Ltd. hosted a conference call regarding the merger (the "10/11/19 Merger Call"). Defendant Wong stated, in pertinent part, as follows:

> We think IMVT-1401 is a promising molecule that has the potential to be a pipeline in a product. So to provide a bit of context, ***we've been tracking the development of IMVT-1401 for several years now as part of our competitive analysis of the FcRn drug class***, which we expect will become a cornerstone therapy in autoantibody-driven disease. We've been ***impressed*** by its ability to be given subcutaneously and ***its robust reduction in IgG levels in comprehensive Phase I program***…Finally, we are excited to have gained the support of the industry-leading life sciences investors, who have collectively agreed to provide over $100 million in connection with this transaction to fund the development of IMVT-1401.

(Emphasis added).

178. The statements referenced above in ¶177 were materially false and misleading when made for the reasons set forth in ¶171 above. Additionally, Defendant Wong's statement, "[w]e've been impressed by its…robust reduction in IgG levels in comprehensive Phase I program" was materially false and misleading because the Phase I program was not "robust" because it did not test for an anticipated risk of elevated cholesterol and it failed to disclose that a reduction in albumin levels may cause an increase in cholesterol.

179. On the 10/11/19 Merger Call, Defendant Salzmann stated, in pertinent part, as follows:

> We've developed a two-pronged strategy. Specifically, ***we strive to be best-in-class in target indications*** where the anti-FcRn approach has already established clinical proof of concept, and first-in-class in target indications with clear biologic rationale and no-in-class competition. To these ends, I'm proud of the many milestones delivered by the Immunovant team this year, including ***completion of a comprehensive Phase 1 program*** demonstrating robust IgG reductions of 78% with simple weekly subcutaneous injections of 680 milligrams. Note that the Immunovant team ran this trial in Australia and Canada and successfully dosed 99 healthy volunteers across cohorts. We've also initiated a ***broad Phase 2 program with both***

> ***first-in-class and best-in-class potential*** in multiple diseases with high unmet patient need. Importantly, IMVT-1401 was also ***generally well tolerated in this good-sized Phase 1 trial***.
>
> * * *
>
> ***Over the next 20 months, we anticipate four data readouts.*** In the first quarter of 2020, we expect to report initial results from our ***Phase 2a study in Graves' Ophthalmopathy,*** a potentially site threatening disease affecting an estimated 15,000 to 20,000 patients in the United States each year. Our Phase 2b study in the same indication is expected to report initial results in early 2021. Additionally, in the first half of 2020, we expect to report top line results for our ***Phase 2a study in myasthenia gravis*** and initiate a pivotal Phase 3 study shortly thereafter.

(Emphasis added).

180. The statements referenced above in ¶179 were materially false and misleading when made for the reasons set forth in ¶171 above. The statements "we strive to be best-in-class in target indications" and "completion of a comprehensive Phase 1 program" were misleading because the Phase 1 program was not "comprehensive" and IMVT-1401 cannot be considered "best-in-class" with such a serious anticipated risk of cholesterol levels and when that risk is not even being examined. The statements about the other clinical studies were misleading because they failed to disclose the studies did not examine cholesterol levels.

181. During the 10/11/19 Merger Call, Defendant Salzmann stated, in pertinent part, as follows:

> [W]e conducted ***a large Phase 1 trial*** with 99 healthy volunteers. And in that trial, you mentioned headaches. So in our highest dose multiple ascending dose cohort, the 680 milligram subcutaneous dose, ***there are actually no headaches in that cohort, and across all the other various cohorts, we didn't see dose-dependent headaches nor did we see any significant prevalence of headaches***. In terms of injection site reactions, the definition of injection site reaction requires pain or tenderness, and we only had across the entire group of 99 subjects. There are only four, three, who received IMVT-1401 and one who received placebo, that had in any injection site pain and that was mild pain that resolved after a short period of time. So, this is a painless injection as we've seen to date. ***In terms of albumin reductions, we did see a dose-dependent reversible and asymptomatic albumin reductions in the Phase 1 trial***.

182. The statements referenced above in ¶181 were materially false and misleading when made for the reasons set forth in ¶171 above.

183. During the 10/11/19 Merger Call, Defendants Salzmann and Wong responded to a question about albumin reductions in which Defendant Salzmann stated, in pertinent part, as follows: "In terms of albumin reductions, we did see dose dependent reversible and asymptomatic albumin reductions in the Phase 1 trial." And Defendant Wong stated, in pertinent part, as follows:

> I would just add that there are – there's – the kind of "perfect knock out model" and that there are patients borne with close to 0% albumin and those people in the literature are generally asymptomatic with the exception of maybe a little bit of occasional edema, but they're basically healthy people.

184. The statements above in ¶183 about a "perfect knock out model" and "asymptomatic" people born with "close to 0% albumin" were materially misleading because Defendant Wong was minimizing the relationship between decreases in serum albumin and increases in cholesterol.

185. On November 25, 2019, the Company announced dosing in ASCEND GO-2, a Phase 2b Trial of IMVT-1401 in patients with Graves' Opthalmopathy in a press release (the "11/25/19 Press Release"), which it filed with the SEC on Form 8-K. Defendant Salzmann was quoted in the 11/25/19 Press Release and stated, in pertinent part, as follows:

> Graves' ophthalmopathy can be a devastating and sight-threatening disease with a dramatic impact on patients' vision and overall well-being. There is an urgent need for more effective and better tolerated treatment options which can be easily administered by physicians or patients. ***By depleting the autoantibodies responsible for this condition, IMVT-1401 has the potential to become a foundational therapy for GO*** and offer patients a convenient subcutaneously-administered treatment option to control their disease[.]

(Emphasis added).

186. The statements referenced above in ¶185 were materially false and misleading when made for the reasons set forth in ¶171 above. "IMVT-1401 has the potential to become a foundational therapy" was misleading because of the anticipated risk of elevated cholesterol levels.

187. On November 27, 2019, Health Sciences Acquisitions Corporation filed a Schedule 14A Proxy Statement (the "11/27/19 Proxy") with the SEC which stated, in pertinent part, as follows:

> ***Dose-dependent and reversible albumin reductions were observed in the single-ascending and multiple-ascending dose cohorts.*** In the 680 mg multiple-ascending dose cohort, most subjects reached nadir before administration of the final dose. Mean reduction in albumin levels at day 28 were 20% in the 340 mg multiple-dose cohort, and 31% in the 680 mg multiple-dose cohort. For subjects in the 340 mg and 680 mg cohorts, the mean albumin levels at day 28 were 37.5 g/L and 32.4 g/L, respectively (normal range 36-51 g/L). ***These reductions were not associated with any AEs or clinical symptoms, and did not lead to any study discontinuations. The clinical relevance of isolated, mild hypoalbuminemia is unknown, however, a hereditary syndrome associated with deficient albumin production has been described (Congenital Analbumenia).*** In this syndrome, ***despite extremely low or absent levels of albumin, those affected have only mild symptoms, including fatigue, low blood pressure and edema***. It is believed that compensatory mechanisms through the production of other proteins may allow for relatively normal physiologic function in this population.

(Emphasis added).

188. The statements referenced above in ¶187 were materially false and misleading when made for the reasons set forth in ¶171 above. Additionally, the statements referenced above that "albumin reductions" were not "associated with any AEs or clinical symptoms, and did not lead to any study discontinuations" were materially false and misleading because the albumin reductions were associated with the adverse events (AEs) of substantially increased cholesterol levels. The statements were also misleading because Immunovant failed to test for cholesterol levels even though it was an anticipated risk that albumin reductions would substantially increase cholesterol levels. Additionally, by stating that there were no "AE's" or "clinical symptoms" or "study discontinuations," the statements created the misleading impression that cholesterol levels were measured as part of the study and the albumin reduction did not substantially increase cholesterol levels.

189. The 11/27/19 Proxy annexed the Share Exchange Agreement, which stated, in pertinent part, as follows:

> 4.27 Preclinical Development and Clinical Trials. The studies, tests, preclinical development and clinical trials, if any, conducted by or on behalf of the Company ***are being conducted in all material respects in accordance with experimental protocols, procedures and controls pursuant to accepted professional and scientific standards for products or product candidates comparable to those being developed by the Company*** and all applicable laws and regulations, including the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. parts 50, 54, 56, 58, 312, and 812. The descriptions of, protocols for, and data and other results of, the studies, tests, development and trials conducted by or on behalf of the Company that have been furnished or made available to the Purchaser or as provided in the Proxy Statement are accurate and ***complete in all material respects*** (other than to the extent certain portions thereof were redacted by the Company). ***The Company is not aware of any studies, tests, development or trials the results of which reasonably call into question the results of the studies, tests, development and trials conducted by or on behalf of the Company***[.]

(Emphasis added).

190. The statements referenced above in ¶189 were materially false and misleading when made for the reasons set forth in ¶171 above. Additionally, contrary to the statement that the clinical trials "are being conducted…in accordance with…accepted professional and scientific standards" was materially false and misleading because Immunovant failed to adhere to good clinical practices as alleged above.

191. On January 17, 2020, Immunovant filed its Form S-1 Registration Statement with the SEC (the "1/17/20 Registration Statement"), which was signed by, among others, Defendants Salzmann, Connealy, Torti, Fromkin, Hughes, Migausky, and Pande. The 1/17/20 Registration Statement stated, in pertinent part, as follows:

> *Phase 1 Clinical Trials of IMVT-1401 in Healthy Volunteers*
>
> As of June 30, 2019, we have dosed 99 healthy volunteers in multi-part, placebo-controlled Phase 1 clinical trials conducted in Australia and Canada, both as an intravenous infusion and as a subcutaneous injection. In these trials, 77 subjects received at least one dose of IMVT-1401 and 22 subjects received placebo. We expect this multi-part, placebo-controlled Phase 1 clinical trial in healthy volunteers

to continue to support its IND submissions to the FDA for IMVT-1401 in each of our current target indications, MG, GO and WAIHA. The preliminary results of this trial are presented below.

192. The 1/17/20 Registration Statement also stated, in pertinent part, as follows:

In May 2019, we initiated dosing in its ASCEND-GO 1 trial, a Phase 2a clinical trial in Canada in patients with GO. We anticipate reporting initial results from this trial in the first quarter of 2020. In October 2019, we initiated dosing in our ASCEND-GO 2 trial, a Phase 2b clinical trial for GO in the United States, Canada and Europe. We plan to report initial results from this trial in early 2021.

193. The 1/17/20 Registration Statement also stated, in pertinent part, as follows:

Safety Data

In our multi-part, placebo-controlled Phase 1 clinical trial, IMVT-1401 has been observed to be well-tolerated with no Grade 3 or Grade 4 AEs and no discontinuations due to AEs. The most commonly reported AE has been mild erythema and swelling at the injection site, which typically resolved within hours and had a similar incidence between subjects receiving IMVT-1401 and placebo. These reactions at the injection site were not considered dose-related and did not increase with multiple administrations of IMVT-1401 in the multiple-dose cohorts. To date, two serious AEs have been reported, both of which have been assessed as unrelated to IMVT-1401 by the study investigator. ***There have been no treatment-related serious AEs reported.***

* * *

Dose-dependent and reversible albumin reductions were observed in the single-ascending and multiple-ascending dose cohorts. In the 680 mg multiple-ascending dose cohort, most subjects reached nadir before administration of the final dose. Mean reduction in albumin levels at day 28 were 20% in the 340 mg multiple-dose cohort, and 31% in the 680 mg multiple-dose cohort. For subjects in the 340 mg and 680 mg cohorts, the mean albumin levels at day 28 were 37.5 g/L and 32.4 g/L, respectively (normal range 36-51 g/L). ***These reductions were not associated with any AEs or clinical symptoms, and did not lead to any study discontinuations.*** The clinical relevance of isolated, mild hypoalbuminemia is unknown, however, a hereditary syndrome associated with deficient albumin production has been described (Congenital Analbumenia). In this syndrome, despite extremely low or absent levels of albumin, those affected have only mild symptoms, including fatigue, low blood pressure and edema. It is believed that compensatory mechanisms through the production of other proteins may allow for relatively normal physiologic function in this population.

(Emphasis added).

194. The statements referenced above in ¶¶191-193 were materially false and misleading when made for the reasons set forth in ¶171 above. The statement "observed to be well-tolerated with no Grade 3 or Grade 4 treatment emergent AEs and no discontinuations due to AEs" was misleading because it gave the impression that there were not elevated cholesterol levels even though Immunovant was not testing for cholesterol.

195. The 1/17/20 Registration Statement also stated, in pertinent part, as follows:

> ***Preclinical Studies of IMVT-1401***
>
> Cynomolgus monkeys were selected as the primary species for preclinical testing, given the high degree of sequence homology to human FcRn and IMVT-1401's strong binding affinity for monkey FcRn. Our partner, HanAll, completed five preclinical studies of IMVT-1401 (referred as HL161BKN for the purposes of these studies) in cynomolgus monkeys. We are conducting two additional studies in cynomolgus monkeys.

196. The statements referenced above in ¶195 were materially false and misleading when made for the reasons set forth in ¶171 above. Immunovant's animal studies revealed substantial increases in cholesterol for animals taking IMVT-1401. Immunovant was not carefully monitoring for the AE of elevated cholesterol and LDL levels.

197. The 1/17/20 Registration Statement also stated, in pertinent part, as follows:

> ***ASCEND-MG Trial***
>
> In August 2019, we initiated dosing in a randomized, blinded, placebo-controlled Phase 2a clinical trial of IMVT-1401 for the treatment of MG. ***The ASCEND-MG trial assesses safety and efficacy of IMVT-1401*** in an anticipated 21 patients with MG symptoms, as defined by MGFA Class II through IVa, and QMG scores greater than or equal to 12…The primary endpoints of this trial are assessment of the safety and tolerability of IMVT-1401 and identification of optimal dosing for Phase 3 administration through measurement of the changes from baseline in levels of total IgG subclasses and anti-AChR IgG…We anticipate reporting top-line results from this trial in the first half of 2020.

* * *

ASCEND-GO 1 Trial

In May 2019, we initiated dosing in our ASCEND-GO 1 trial, an open label single-arm Phase 2a clinical trial of IMVT-1401 in Canada in patients with GO. Patients recruited for this trial have moderate-to-severe active GO with confirmed autoantibodies to TSHR. An anticipated eight patients will be dosed weekly with subcutaneous injections for six weeks. This trial will utilize an induction and maintenance strategy, using only subcutaneous injections. Patients will receive a 680 mg dose for the first two administrations of study followed by a 340 mg dose for the final four administrations. The primary endpoints of this trial will be safety and tolerability of IMVT-1401 over the six-week treatment period, as well as the change from baseline in levels of anti-TSHR antibodies, total IgG antibodies and IgG antibodies by subclasses…We anticipate reporting initial results from this trial in the first quarter of 2020.

* * *

ASCEND-GO 2 Trial

In October 2019, we initiated dosing in our ASCEND-GO 2 trial, a randomized, masked, placebo-controlled Phase 2b clinical trial in 77 patients with moderate-to-severe active GO with confirmed autoantibodies to TSHR. The ASCEND-GO-2 trial explores the potential of IMVT-1401 to improve proptosis, ***and assesses the safety and tolerability of IMVT-1401 in this population***. Patients in this trial will be treated with one of three doses of IMVT-1401 (680 mg, 340 mg or 255 mg) or placebo administered weekly by subcutaneous injection for 12 weeks. The primary endpoints of this trial are the proptosis responder rate measured at week 13, defined as the percentage of patients with a greater than or equal to 2 mm reduction in proptosis in the study eye without deterioration in the fellow eye, and safety and tolerability… We anticipate reporting initial results from this trial in early 2021.

* * *

ASCEND-WAIHA Trial

In November 2019, we submitted our IND to the FDA for WAIHA and, in December 2019, our IND was cleared for Phase 2 trial initiation. We plan to report initial results from the Phase 2a WAIHA study in the fourth quarter of 2020. The ASCEND-WAIHA trial will explore the potential of IMVT-1401 to increase hemoglobin levels and assess the safety and tolerability of IMVT-1401 in this population. Patients in this trial will be treated with one of two doses of IMVT-1401 (680 mg or 340 mg) administered weekly by subcutaneous injection for 12 weeks. The primary endpoint of this trial is the proportion of responders, defined as patients achieving a hemoglobin level of at least 10 g/dL and at least a 2 g/dL increase from baseline. Secondary endpoints include change from baseline in other hematologic and chemistry parameters, time to response, patient reported outcome measures, total IgG antibodies and IgG antibodies by subclasses. We plan to report initial results from the first treatment cohort of this trial in the fourth quarter of 2020.

(Emphasis added).

198. The statements referenced above in ¶197 were materially false and misleading when made for the reasons set forth in ¶171 above. The statements "[t]he ASCEND MG trial assesses safety and efficacy of IMVT-1401" were misleading because Immunovant failed to test cholesterol levels.

199. The 1/17/20 Registration Statement also stated, in pertinent part, as follows:

> Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated…
>
> - Phase 1 — The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism, distribution and elimination of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.
>
> - Phase 2 — The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
>
> - Phase 3 — The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

200. The statements referenced above in ¶199 were materially false and misleading when made for the reasons set forth in ¶171 above. The statements about Phase 1 studies being "designed to test the safety" and Phase 2 studies to "identify possible adverse side effects and safety risks" because Immunovant had not tested for "safety," "possible adverse side effects and safety risks" related to elevated levels of cholesterol in connection with IMVT-1401.

201. On February 14, 2020, the Company announced its financial and operational results for the third quarter 2019, for the period ended December 31, 2019 ("3Q19"), and for the nine months ending December 31, 2019 in a press release (the "2/14/20 Press Release"), which it filed with the SEC on Form 8-K. Defendant Salzmann was quoted in the 2/14/20 Press Release and stated, in pertinent part, as follows: "I'm also proud of the team for getting IND clearance to begin our Phase 2a trial of IMVT-1401 in warm autoimmune hemolytic anemia. We look forward to four exciting data readouts between now and early 2021."

202. The statements referenced above in ¶201 were materially false and misleading when made for the reasons set forth in ¶171. The statement about "IND clearance" was materially false and misleading because it failed to disclose that Immunovant failed to advise the FDA that its animal studies for IMVT-1401 revealed substantial increases in cholesterol. The statements were also misleading because they failed to disclose that the referenced Phase 2a clinical trial was not designed to test for cholesterol.

203. On February 14, 2020, Immunovant filed its quarterly report on Form 10-Q with the SEC for 3Q19 (the "3Q19 Form 10-Q"), which was signed by Defendants Salzmann and Connealy. The 3Q19 Form 10-Q stated, in pertinent part, as follows:

> In August 2019, we initiated dosing in our ASCEND-MG trial, a Phase 2a clinical trial in patients with MG. We plan to report top-line results from this trial in the first half of 2020. In May 2019, we initiated dosing in our ASCEND-GO 1 trial, a Phase 2a clinical trial in Canada in patients with GO. We anticipate reporting initial results from this trial in the first quarter of 2020. Enrollment is ongoing in our ASCEND-GO 2 trial, a Phase 2b clinical trial for GO in the United States, Canada and Europe. We plan to report initial results from this trial in early 2021. In November 2019, we submitted our investigational new drug application, or IND, to the U.S. Food and Drug Administration, or the FDA, for WAIHA, and in December 2019, our IND was cleared for Phase 2 trial initiation. We plan to report initial results from the Phase 2a WAIHA study in the fourth quarter of 2020.

204. The statements referenced above in ¶203 were materially false and misleading when made for the reasons set forth in ¶171. The statement "our IND was cleared for Phase 2 trial

initiation" was materially false and misleading because it failed to disclose that Immunovant failed to advise the FDA that its animal studies for IMVT-1401 revealed substantial increases in cholesterol. The statements were also misleading because they failed to disclose that the referenced Phase 2a clinical trial was not designed to test for cholesterol.

205. On February 25, 2020, the Company presented at the 9th Annual SVB Leerink Global Healthcare Conference (the "SVB Conference"). Defendant Salzmann was quoted at the SVB Conference and stated, in pertinent part, as follows:

> So hypoalbuminemia, if you look at up, is the result of some very serious diseases. So normally if someone who has hypoalbuminemia, your differential diagnosis of physician might be severe liver disease, severe kidney disease, nephrotic syndrome, globally severe malnutrition but generally, hypoalbuminemia is part of the cause – I'm sorry, as a result of the condition, not a cause of a problem. In this case, we know what's causing the low albumin, which is a direct hindrance at the binding site. So the Fc receptor also recycles albumin and different assets have more or less interruption of that albumin binding site.
>
> We have a little bit, and ***we did see a 20% to 30% reduction in albumin that leveled off, depending on the dose, 20% In the 340 arm, 30% in the 680 arm. That's not something that was associated with any adverse events or edema in the Phase 1 trial. And it's pretty hard to find any published literature or expert opinion on what the sequelae of a albumin – of a mild albumin reduction would be. So, we're not seeing any issues to date.***

(Emphasis added).

206. The statements referenced above in ¶205 were materially false and misleading when made for the reasons set forth in ¶171. The statement that the "20% to 30% reduction in albumin" was not "associated with any adverse events or edema in the Phase 1 trial" was materially false and misleading because the reduction in albumin was associated with the anticipated risk of increased cholesterol and since Immunovant failed to test for cholesterol he did not have a reasonable basis or access to sufficient information to make that statement.

207. During the SVB Conference, Defendant Salzmann stated, in pertinent part, as follows: "I'm very, very excited about our thyroid eye disease program because it's an area of a lot

of recent innovation, but still tremendous remaining opportunity." Defendant Salzmann also stated, in pertinent part, as follows:

> I mean, first of all, it's important to say that we have two programs in thyroid eye disease. And one doesn't gate the other. So, we started them simultaneously for different reasons. So the larger trial, which reads out at the beginning of 2021, that's a placebo-controlled multi-dose study with a 12-week endpoint, which I think is a more appropriate endpoint for a potential registration trial. This first trial that you referenced, Tom, that is going to read out this quarter is a primarily a pharmacodynamic trial. It's an open-label trial that is testing a different dosing regimen. So, two doses at 680 milligrams and then four doses at 340 milligrams. So, six weeks of therapy, but two different doses. ***And the primary endpoints are safety and tolerability*** and change in IgG level. But we will be measuring proptosis responder rate or change in proptosis scores and change in the clinical activity score, CAS, of course across this time window. And teprotumumab showed the result as early as six weeks. So, we would expect to see some as well.

(Emphasis added).

208. The statements referenced above in ¶207 were materially false and misleading when made for the reasons set forth in ¶171. The statement that the "primary endpoints are safety and tolerability" was materially misleading because safety tests were inadequate because Immunovant failed to test for cholesterol.

209. On March 30, 2020, the Company announced clinical results from a Phase 2a proof-of-concept study of IMVT-1401 in a press release (the "3/30/20 Press Release"), which it filed with the SEC on Form 8-K. Defendant Salzmann was quoted in the 3/30/20 Press Release and stated, in pertinent part, as follows:

> We are very excited by the initial results of this trial…[t]hese results provide an early proof-of-concept of the potential for IMVT-1401 to ultimately become a ***safe and effective treatment*** for patients suffering from Thyroid Eye Disease…***[w]e look forward to reporting the study's full results, including detailed lab observations and 12 weeks of follow up data, at an upcoming medical meeting.***

(Emphasis added).

210. The statements referenced above in ¶209 were materially false and misleading when made for the reasons set forth in ¶171. Defendant Salzmann did not have a reasonable basis to state

that IMVT-1401 had potential to be "safe" because Immunovant failed to test cholesterol levels. Additionally, contrary to Defendant Salzmann's statement, he did not have "detailed lab observations" because the clinical trial did not test cholesterol.

211. Also on March 30, 2020, the Company held a conference call with analysts and investors (the "3/30/20 Conf Call") to discuss information set forth in the 3/30/20 Press Release. During the 3/30/20 Conf Call, Defendant Salzmann stated, in pertinent part, as follows:

> I would like to start off by expressing how thrilled we are about the ***positive clinical results we are announcing today in thyroid eye disease.*** As the only subcutaneous therapy in clinical development for thyroid eye disease, we believe IMVT-1401 has the potential to be life-changing for patients, and we couldn't be happier with the outcome of this small proof-of-concept trial.

212. The statements referenced above in ¶211 were materially false and misleading when made for the reasons set forth in ¶171.

213. During the 3/30/20 Conf Call, Defendant Salzmann stated, in pertinent part, as follows:

> ASCEND GO-1 is the first trial of an anti-FcRn in thyroid eye disease. We had 2 major objectives for this trial: first, the study was designed to test the pharmacodynamic response to a loading dose regimen; second, ***the study was designed to examine the initial safety and efficacy of IMVT-1401 in thyroid eye disease.*** Patients were treated with 2 weekly 680-milligram loading doses, followed by 4 weekly 340-milligram maintenance doses for a total of 6 weeks of treatment. Further study protocol, all patients included were positive for antibodies directed at the thyroid-stimulating hormone receptor.
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> We are also pleased to report that the safety and tolerability profile we observed in ASCEND GO-1 was in line with our expectations from our Phase 1 study in 99 healthy volunteers. We saw no serious adverse events or SAEs, no withdrawals due to adverse events and no headaches were reported in this trial. All adverse events were mild or moderate. For albumin, we observed an average reduction of 24%. Albumin changes were asymptomatic in this trial as they were in Phase 1.
>
> * * *

> Thyroid eye disease Phase IIb study. Results are still possible in the first half of 2021. This study does have a meaningful number of European sites, which could prove challenging, depending on how the enrollment environment evolves there. However, I expect the positive results we're announcing today to be a tailwind. In other words, now that our Phase IIa initial results are available, we are hopeful we'll be able to reaccelerate enrollment once our sites in Europe and North America recover. We expect to have more clarity by Q3 of this year.

(Emphasis added).

214. The statements referenced above in ¶213 were materially false and misleading when made for the reasons set forth in ¶171. Additionally, the statement "designed to examine the initial safety" was misleading because Immunovant failed to test the safety with respect to cholesterol levels and the attendant potential for an increased risk of cardiovascular disease.

215. During the 3/30/20 Conf Call, Defendant Salzmann stated, in pertinent part, as follows:

> I think on the safety side, the FDA is going to look at the full range of a data package for any asset that's submitted. ***I think what we're really encouraged by in terms of our data to date is that all the adverse events that have been reported, both in our Phase I trial with healthy volunteers as well as in this trial, were just mild or moderate. We haven't had any SAEs.*** And although the FDA, I don't think, would be particularly concerned about headaches, patients certainly would be, and so we are really encouraged to see no headaches in this trial, which is consistent with the type of data we presented from Phase I as well.

(Emphasis added).

216. The statements referenced above in ¶215 were materially false and misleading when made for the reasons set forth in ¶171. Additionally, the statements "all the adverse events that have been reported, both in our Phase I trial with healthy volunteers as well as in this trial, were just mild or moderate. We haven't had any SAEs" were materially false and misleading because Defendant Salzmann new, or recklessly disregarded, that the animal studies showed a potential adverse event for cholesterol and that Immunovant was not testing for this anticipated risk.

217. On or about April 10, 2020, the Company filed its Form S-1 Registration Statement with the SEC and Prospectus (the "4/10/20 Registration Statement"). The 4/10/20 Registration Statement was filed with respect to the sale of 11,389,969 shares of Immunovant common stock that may be sold by several selling stockholders from time to time. More than 4 million shares were registered with respect to shares beneficially owned by entities affiliated with Defendant Wong. The 4/10/20 Registration Statement contained the following table listing the selling shareholders:

Please see the section titled "Plan of Distribution" for further information regarding the stockholders' method of distributing these shares.

	Shares of Common Stock			
Name	Number Beneficially Owned Prior to Offering(1)	Number Registered for Sale Hereby(2)	Number Beneficially Owned After Offering	Percent Owned After Offering
RTW Master Fund, Ltd.(3)	3,235,952	3,235,952	—	—
RTW Innovation Master Fund, Ltd.(3)	1,037,580	1,037,580	—	—
RTW Venture Fund Limited(3)	152,574	152,574	—	—
HanAll BioPharma Co., Ltd.(4)	636,805	636,805	—	—
Biotechnology Value Fund, L.P.	493,952	493,952	—	—
Biotechnology Value Fund II, L.P.	401,724	401,724	—	—
Biotechnology Value Trading Fund OS, L.P.	71,925	71,925	—	—
MSI BVF SPV L.L.C.	32,395	32,395	—	—
Health Sciences Holdings, LLC (Sponsor)(5)(6)	2,875,000	2,875,000	—	—

218. The 4/10/20 Registration Statement discussed the background of the Company, the clinical and pre-clinical trials of IMVT-1401, and the prospects, efficacy and safety of IMVT-1401. The 4/10/20 Registration Statement stated, in pertinent part, as follows:

> In August 2019, we initiated dosing in our ASCEND MG trial, a Phase 2a clinical trial in patients with MG. We plan to report top-line results from this trial in the third quarter of calendar year 2020.
>
> * * *
>
> In May 2019, we initiated dosing in our ASCEND GO-1 trial, a Phase 2a clinical trial in Canada in patients with TED. We announced initial results from this trial in March 2020. Enrollment is ongoing in our ASCEND GO-2 trial, a Phase 2b clinical trial for TED in the United States, Canada and Europe. We currently plan to report top-line results from this trial in the first half of calendar year 2021.
>
> * * *
>
> In November 2019, we submitted our investigational new drug application ("IND") to the U.S. Food and Drug Administration ("FDA") for WAIHA and, in December 2019, our IND was cleared for Phase 2 trial initiation. We plan to report top-line

> results for the high-dose cohort from our ASCEND WAIHA trial, a Phase 2a clinical trial in patients with WAIHA, by the end of calendar year 2020.
>
> * * *
>
> On March 30, 2020, we announced initial results from the ASCEND GO-1 trial. Mean reduction in total IgG levels from baseline to end of treatment was 65%. As evaluated at the end of treatment, four of seven patients (57%) improved by ³ 2 points on the Clinical Activity Score (CAS).

219. The statements referenced above in ¶¶217-218 were materially false and misleading when made for the reasons set forth in ¶171 above.

220. The 4/10/20 Registration Statement stated, in pertinent part, as follows:

> In several nonclinical studies and Phase 1 clinical trials in healthy volunteers, intravenous and subcutaneous delivery of IMVT-1401 ***demonstrated dose-dependent IgG antibody reductions and was observed to be well tolerated.*** In the highest dose cohort from the multiple-ascending dose portion of the Phase 1 clinical trial, four weekly subcutaneous administrations of 680 mg resulted in a mean maximum reduction of serum IgG levels of 78%, and the standard deviation of the reduction was 2%. In addition, no headaches, an adverse event seen with some FcRn agents, have been noted to date in any of the subjects receiving IMVT-1401 in the 680 mg multiple-dose cohort.

221. The statements referenced above in ¶220 were materially false and misleading when made for the reasons set forth in ¶171 above. The statement that "several nonclinical studies and Phase 1 clinical trials" was "observed to be well tolerated" was untrue because the animal studies revealed substantial increases in cholesterol, and it was unknown whether the "Phase 1 clinical trial" was "well tolerated" because Immunovant failed to test cholesterol levels.

222. The 4/10/20 Registration Statement stated, in pertinent part, as follows:

> *Phase 1 Clinical Trials of IMVT-1401 in Healthy Volunteers*
>
> As of June 30, 2019, we have dosed 99 healthy volunteers in multi-part, placebo-controlled Phase 1 clinical trials conducted in Australia and Canada, both as an intravenous infusion and as a subcutaneous injection. In these trials, 77 subjects received at least one dose of IMVT-1401 and 22 subjects received placebo. ***We expect this multi-part, placebo-controlled Phase 1 clinical trial in healthy volunteers to continue to support its IND submissions to the FDA for IMVT-1401 in each of our current target indications, MG, TED and WAIHA***.

223. The statements referenced above in ¶222 were materially false and misleading when made for the reasons set forth in ¶171 above.

224. The 4/10/20 Registration Statement stressed the safety of IMVT-1401, stating, in pertinent part, as follows:

> ***Safety Data***
>
> ***In our multi-part, placebo-controlled Phase 1 clinical trial, IMVT-1401 has been observed to be well-tolerated with no Grade 3 or Grade 4 AEs and no discontinuations due to AEs. The most commonly reported AE has been mild erythema and swelling at the injection site, which typically resolved within hours and had a similar incidence between subjects receiving IMVT-1401 and placebo.*** These reactions at the injection site were not considered dose-related and did not increase with multiple administrations of IMVT-1401 in the multiple-dose cohorts. To date, two serious AEs have been reported, both of which have been assessed as unrelated to IMVT-1401 by the study investigator. ***There have been no treatment-related serious AEs reported.***
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> * * *
>
> Dose-dependent and reversible ***albumin reductions were observed*** in the single-ascending and multiple-ascending dose cohorts. In the 680 mg multiple-ascending dose cohort, most subjects reached nadir before administration of the final dose. Mean reduction in albumin levels at day 28 were 20% in the 340 mg multiple-dose cohort, and 31% in the 680 mg multiple-dose cohort. For subjects in the 340 mg and 680 mg cohorts, the mean albumin levels at day 28 were 37.5 g/L and 32.4 g/L, respectively (normal range 36-51 g/L). ***These reductions were not associated with any AEs or clinical symptoms, and did not lead to any study discontinuations.*** The clinical relevance of isolated, mild hypoalbuminemia is unknown, however, a hereditary syndrome associated with deficient albumin production has been described (Congenital Analbumenia). In this syndrome, ***despite extremely low or absent levels of albumin, those affected have only mild symptoms***, including fatigue, low blood pressure and edema. It is believed that compensatory mechanisms through the production of other proteins may allow for relatively normal physiologic function in this population.

(Emphasis added).

225. The statements referenced above in ¶224 were materially false and misleading when made for the reasons set forth in ¶171 above. The statement "observed to be well-tolerated with no Grade 3 or Grade 4 treatment emergent AEs and no discontinuations due to AEs" was misleading

because Immunovant had observed substantially elevated cholesterol levels in the animal studies, and it was an anticipated risk that there could also be substantially elevated levels in humans but cholesterol levels were not monitored. The statements about a lack of AEs were also misleading because it gave the impression that there were not elevated cholesterol levels even though Immunovant was not testing for cholesterol. Additionally, the statements referenced above that "albumin reductions" were not "associated with any AEs or clinical symptoms, and did not lead to any study discontinuations" were materially false and misleading because the albumin reductions were associated with the adverse events (AEs) of substantially increased cholesterol levels. The statements were also misleading because Immunovant failed to test for cholesterol levels even though it was an anticipated risk that albumin reductions would substantially increase cholesterol levels. Additionally, by stating that there were no "AE's" or "clinical symptoms" or "study discontinuations," the statements created the misleading impression that cholesterol levels were measured as part of the study and the albumin reduction did not substantially increase cholesterol levels.

226. The 4/10/20 Registration Statement discussed the IMVT-1401 animal studies, stating, in pertinent part, as follows:

> ***Nonclinical Studies of IMVT-1401***
>
> Cynomolgus monkeys were selected as the primary species for nonclinical testing, given the high degree of sequence homology to human FcRn and IMVT-1401's strong binding affinity for monkey FcRn. Our partner, HanAll, completed five nonclinical studies of IMVT-1401 (referred as HL161BKN for the purposes of these studies) in cynomolgus monkeys. We are conducting two additional studies in cynomolgus monkeys.

227. The statement referenced above in ¶226 was materially false and misleading when made for the reasons set forth in ¶171.

228. The 4/10/20 Registration Statement stated, in pertinent part, as follows:

ASCEND MG Trial

In August 2019, we initiated dosing in a randomized, blinded, placebo-controlled Phase 2a clinical trial of IMVT-1401 for the treatment of MG. ***The ASCEND MG trial assesses safety and efficacy of IMVT-1401*** in an anticipated 21 patients with MG symptoms, as defined by MGFA Class II through IVa, and QMG scores greater than or equal to 12…The primary endpoints of this trial are assessment of the safety and tolerability of IMVT-1401 and identification of optimal dosing for Phase 3 administration through measurement of the changes from baseline in levels of total IgG subclasses and anti-AChR IgG… We anticipate reporting top-line results from this trial in the third quarter of calendar year 2020.

* * *

ASCEND GO-1 Trial

In May 2019, we initiated dosing in our ASCEND GO-1 trial, an open label single-arm Phase 2a clinical trial of IMVT-1401 in Canada in patients with TED. We announced initial results from this trial in March 2020. Patients recruited for this trial have moderate-to-severe active TED with confirmed autoantibodies to TSHR. A total of seven patients were dosed weekly with subcutaneous injections for six weeks. The trial utilized an induction and maintenance strategy, using only subcutaneous injections. Patients received a 680 mg dose for the first two administrations of study followed by a 340 mg dose for the final four administrations. The primary endpoints of this trial are safety and tolerability of IMVT-1401 over the six-week treatment period, as well as the change from baseline in levels of anti-TSHR antibodies, total IgG antibodies and IgG antibodies by subclasses…***The safety and tolerability profile observed was consistent with the prior Phase 1 trial of IMVT-1401 in 99 healthy volunteers. All adverse events were mild or moderate and there were no headaches reported.***

* * *

ASCEND GO-2 Trial

In October 2019, we initiated dosing in our ASCEND GO-2 trial, a randomized, masked, placebo-controlled Phase 2b clinical trial in 77 patients with moderate-to-severe active TED with confirmed autoantibodies to TSHR. The ASCEND GO-2 trial explores the potential of IMVT-1401 to improve proptosis, and ***assesses the safety and tolerability of IMVT-1401 in this population.*** Patients in this trial will be treated with one of three doses of IMVT-1401 (680 mg, 340 mg or 255 mg) or placebo administered weekly by subcutaneous injection for 12 weeks. The primary endpoints of this trial are the proptosis responder rate measured at week 13, defined as the percentage of patients with a greater than or equal to 2 mm reduction in proptosis in the study eye without deterioration in the fellow eye, and safety and tolerability… We currently anticipate reporting top-line results from this trial in the first half of calendar year 2021.

* * *

ASCEND WAIHA Trial

In November 2019, we submitted our IND to the FDA for WAIHA and, in December 2019, our IND was cleared for Phase 2 trial initiation. We plan to report top-line results for the high-dose cohort from our ASCEND WAIHA trial, a Phase 2a clinical trial in patients with WAIHA, by the end of calendar year 2020. The ASCEND WAIHA trial will explore the potential of IMVT-1401 to increase hemoglobin levels and assess the safety and tolerability of IMVT-1401 in this population. Patients in this trial will be treated with one of two doses of IMVT-1401 (680 mg or 340 mg) administered weekly by subcutaneous injection for 12 weeks. The primary endpoint of this trial is the proportion of responders, defined as patients achieving a hemoglobin level of at least 10 g/dL and at least a 2 g/dL increase from baseline. Secondary endpoints include change from baseline in other hematologic and chemistry parameters, time to response, patient reported outcome measures, total IgG antibodies and IgG antibodies by subclasses. We plan to report top-line results for the high-dose cohort from the first treatment cohort of this trial by the end of calendar year 2020.

(Emphasis added).

229. The statements referenced above in ¶228 were materially false and misleading when made for the reasons set forth in ¶171 above. The statement "[t]he ASCEND MG trial assesses safety and efficacy of IMVT-1401" was misleading because Immunovant failed to test cholesterol levels. The statements,"[t]he safety and tolerability profile observed was consistent with the prior Phase 1 trial of IMVT-1401" and "[a]ll AEs were mild or moderate" were misleading because Immunovant failed to test for the anticipated risk of elevated cholesterol levels and Immunovant, therefore, could not have been aware of "all AEs" that should have been tested under Clinical Good Practices.

230. The 4/10/20 Registration Statement stated, in pertinent part, as follows:

Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated…

- Phase 1 — The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism,

distribution and elimination of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.

- Phase 2 — The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- Phase 3 — The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

231. The statements referenced above in ¶230 were materially false and misleading when made for the reasons set forth in ¶171 above. The statements about Phase 1 studies being "designed to test the safety" and Phase 2 studies to "identify possible side effects and safety risks" because Immunovant had not tested for "safety," "possible adverse side effects and safety risks" related to elevated levels of cholesterol in connection with IMVT-1401.

232. On April 14, 2020, the Company filed its 424B4 Prospectus (the "4/14/20 Prospectus") with the SEC in connection with a follow-on offering of 8,359,448 shares of Immunovant common stock at a price of $14.50 per share. After the full exercise of the underwriters' allotment, $139.4 million was raised from investors. The 4/14/20 Prospectus contained nearly identical representations about the Company, the testing of IMVT-1401, and the prospects and safety of IMVT-1401 as referenced in ¶¶217, 218, 220, 222, 224, 226, 228, and 230 above.

233. The statements referenced above in ¶232 were materially false and misleading when made for the reasons set forth in ¶¶219, 221, 223, 225, 227, 229, and 231.

234. On June 29, 2020, the Company announced its financial and operational results for the fourth quarter 2020, for the period ended March 31, 2020 ("4Q20"), and for the full year 2020 for the year ended March 31, 2020 ("FY20") in a press release (the "6/29/20 Press Release"), which it filed with the SEC on Form 8-K. The 6/29/20 Press Release stated, in pertinent part, as follows:

> In March, Immunovant announced positive clinical results from ASCEND GO-1, a Phase 2a trial of IMVT-1401 in Thyroid Eye Disease (TED), which ***reaffirmed IMVT-1401's prior safety and pharmacodynamic findings and demonstrated encouraging potential efficacy for patients with TED***. Complementing these findings, two recent successful studies for other drug candidates with the same mechanism of action provided strong clinical validation in MG and demonstrated a within-study relationship between the degree of IgG lowering and the magnitude of clinical benefit in MG. ***With proof-of-biology now established for anti-FcRn agents in MG, Immunovant has chosen to accelerate Phase 3 development of IMVT-1401 in MG. "Immunovant expects to engage the FDA on the design and conduct of the pivotal program and we expect the Agency's feedback to be an important part of the final plan,"*** said Dr. Salzmann.
>
> * * *
>
> Immunovant expects to report results from ASCEND MG, a Phase 2a trial of IMVT-1401 in MG, in late calendar Q3 or early calendar Q4. As previously communicated, results from the high dose cohort of ASCEND WAIHA, a Phase 2a trial of IMVT-1401 in Warm Autoimmune Hemolytic Anemia (WAIHA) are still possible by the end of the second half of 2020 and results from ASCEND GO-2, a Phase 2b trial of IMVT-1401 in TED, are still possible in the first half of 2021. Immunovant intends to provide an update on its anticipated clinical development timelines for TED and WAIHA in the third quarter of calendar year 2020.

(Emphasis added).

235. The statements referenced above in ¶234 were materially false and misleading when made for the reasons set forth in ¶171 above.

236. On June 29, 2020, Immunovant filed its annual report on Form 10-K with the SEC for FY20 (the "2020 Form 10-K"), which was signed by Defendants Salzmann, Connealy, Torti, Fromkin, Hughes, Migausky, Pande, and Venker. The 2020 Form 10-K contained nearly identical representations about Immunovant, the testing of IMVT-1401, and the potential and safety of IMVT-

1401, as contained in the 4/14/20 Prospectus and 4/10/20 Registration Statement, as referenced above in ¶¶217, 218, 220, 222, 224, 226, 228, 230, and 232.

237. The statements referenced above in ¶236 were materially false and misleading when made for the reasons set forth in ¶¶219, 221, 223, 225, 227, 229, 231, and 233.

238. For example, the 2020 Form 10-K discussed the safety of IMVT-1401, stating, in pertinent part, as follows:

> *Safety Data*
>
> ***In our multi-part, placebo-controlled Phase 1 clinical trial, IMVT-1401 has been observed to be well-tolerated with no Grade 3 or Grade 4 treatment-emergent AEs and no discontinuations due to AEs. The most commonly reported AE has been mild erythema and swelling at the injection site, which typically resolved within hours and had a similar incidence between subjects receiving IMVT-1401 and placebo.*** These reactions at the injection site were not considered dose-related and did not increase with multiple administrations of IMVT-1401 in the multiple-dose cohorts. To date, two serious AEs have been reported, both of which have been assessed as unrelated to IMVT-1401 by the study investigator. ***There have been no treatment-related serious AEs reported.***
>
> * * *
>
> Dose-dependent and reversible albumin reductions were observed in the single-ascending and multiple-ascending dose cohorts. In the 680 mg multiple-ascending dose cohort, most subjects reached nadir before administration of the final dose. Mean reduction in albumin levels at day 28 were 20% in the 340 mg multiple-dose cohort, and 31% in the 680 mg multiple-dose cohort. For subjects in the 340 mg and 680 mg cohorts, the mean albumin levels at day 28 were 37.5 g/L and 32.4 g/L, respectively (normal range 36-51 g/L). ***These reductions were not associated with any AEs or clinical symptoms and did not lead to any study discontinuations.*** The clinical relevance of isolated, mild hypoalbuminemia is unknown, however, a hereditary syndrome associated with deficient albumin production has been described (Congenital Analbumenia). In this syndrome, despite extremely low or absent levels of albumin, those affected have only mild symptoms, including fatigue, low blood pressure and edema. It is believed that compensatory mechanisms through the production of other proteins may allow for relatively normal physiologic function in this population.

(Emphasis added).

239. The statements referenced above in ¶238 were materially false and misleading when made for the reasons set forth in ¶171 above. The statement "observed to be well-tolerated with no

Grade 3 or Grade 4 treatment emergent AEs and no discontinuations due to AEs" was misleading because Immunovant had observed substantially elevated cholesterol levels in the animal studies, and it was an anticipated risk that there would also be substantially elevated levels in humans. The statements about a lack of AEs were also misleading because it gave the impression that there were not elevated cholesterol levels even though Immunovant was not testing for cholesterol. Additionally, the statements referenced above that "albumin reductions" were not "associated with any AEs or clinical symptoms, and did not lead to any study discontinuations" were materially false and misleading because the albumin reductions were associated with the adverse events (AEs) of substantially increased cholesterol levels. The statements were also misleading because Immunovant failed to test for cholesterol levels even though it was an anticipated risk that albumin reductions would substantially increase cholesterol levels. Additionally, by stating that there were no "AE's" or "clinical symptoms" or "study discontinuations," the statements created the misleading impression that cholesterol levels were measured as part of the study and the albumin reduction did not substantially increase cholesterol levels.

240. On August 25, 2020, the Company announced results from the multi-center, placebo-controlled Phase 2a trial of IMVT-1401 in a press release (the "8/25/20 Press Release"), which it filed with the SEC on Form 8-K. The 8/25/20 Press Release stated, in pertinent part, as follows:

> Consistent with previously reported Phase 1 results, ***IMVT-1401 was observed to be generally safe and well-tolerated with no serious adverse events (SAEs), no withdrawals due to adverse events (AEs***), and no imbalance in headaches. Mean reductions in total serum IgG from baseline for the 340 mg and 680 mg cohorts were 59% and 76%, respectively. "We are absolutely thrilled with the results of this trial," said Pete Salzmann, M.D., Chief Executive Officer of Immunovant. "The clinical benefits we observed in this trial provide strong support that IMVT-1401 might ultimately become a ***best-in-class*** anti-FcRn agent for MG patients.

241. The statements referenced above in ¶240 were materially false and misleading when made for the reasons set forth in ¶171 above. The statement "IMVT-1401 was observed to be

generally safe and well-tolerated with no serious adverse events (SAEs), no withdrawals due to adverse events (AEs)" was materially false and misleading when made because Defendant Salzmann lacked a reasonable basis for this statement because Immunovant failed to test for an anticipated risk of elevated cholesterol levels.

242. On August 25, 2020, the Company held a conference call for analysts and investors (the "8/25/20 Conf Call"). During the 8/25/20 Conf Call, Defendant Salzmann stated, in pertinent part, as follows:

> In line with our prior results, ***IMVT-1401 was observed to be generally well tolerated with no grade 3 treatment-emergent adverse*** events, no withdrawals due to adverse events and no imbalances in specific AEs. Reductions in albumin were also consistent with prior studies, with a 16% reduction observed in the 340-milligram arm and a 26% reduction observed in the 680-milligram arm. All albumin reductions were asymptomatic.
>
> * * *
>
> ***On the safety and tolerability side, our results were consistent with prior Phase I and Phase II results for IMVT-1401.*** Namely no severe adverse events, no withdrawals due to adverse events and a rate of mild to moderate adverse events that was well balanced with placebo.

(Emphasis added).

243. The statements referenced above in ¶242 were materially false and misleading when made for the reasons set forth in ¶171 above. Additionally, Defendant Salzmann's lacked a reasonable basis to represent that IMVT-1401 was "generally well tolerated" and there were "no severe adverse events" because Immunovant was not testing for the anticipated risk of elevated cholesterol.

244. On the 8/25/20 Conf Call, Defendant Salzmann stated, in pertinent part, as follows: "Our thyroid eye disease Phase IIb trial remains on track, and we expect to share results in the first half of 2021."

245. The statement referenced in ¶244 above was materially false and misleading because Defendant Salzmann failed to disclose that the undisclosed safety issues of substantially elevated LDL and cholesterol levels, if publicly disclosed, threatened to delay and/or derail IMVT-1401's prospects for commercial viability and profitability.

246. On or about September 1, 2020, Immunovant filed the September 2020 Offering Documents in connection with the September 2020 Offering. The representations in the September 2020 Offering Documents discussed Immunovant, the trials for IMVT-1401, and the efficacy and safety of IMVT-1401 as referenced in ¶¶95, 96, 98, 100, 102, 104, 106, 107, 109, 111, and 113 above. The September 2020 Offering Documents were materially false and misleading when made for the reasons set forth in ¶¶97, 99, 101, 103, 105, 108, 110, 112, and 114.

247. On November 12, 2020, the Company announced its financial and operational results for the second quarter 2020, for the period ended September 30, 2020 ("2Q20") in a press release (the "11/12/20 Press Release"), which it filed with the SEC on Form 8-K. In the 11/12/20 Press Release, Defendant Salzmann was quoted and stated, in pertinent part, as follows: "Our team made outstanding operational and strategic progress during the fiscal second quarter…[f]irst, we reported positive topline results from our randomized, placebo-controlled trial of IMVT-1401 in patients with moderate-to-severe Myasthenia Gravis (MG)."

248. The statement referenced above in ¶247 was materially false and misleading when made because Defendant Salzmann failed to disclose that the "reported positive topline results" failed to incorporate testing for the anticipated risk of substantially elevated cholesterol levels.

249. On November 12, 2020, the Company participated in the Credit Suisse Healthcare Conference (the "11/12/20 Conf Call"). During the 11/12/20 Conf Call, Defendant Salzmann stated, in pertinent part, as follows:

> And what did we see going back here to the summary of our Phase IIa open-label proof-of-concept trial? So first of all, ***we saw IgG reduction, which was as expected***. This was primarily a 340-milligram regimen for 6 weeks. ***So the 65% reduction in IgG was consistent with what we had modeled this regimen would produce***. And then in terms of clinical activity score and proptosis response and double vision, we saw degrees of improvement, which were really, really encouraging, meaningful to patients and largely consistent with the data published by teprotumumab at 6 weeks. Of course, this is a small study. And that trial had 24 weeks for a primary endpoint. So comparing a 6-week open-label to a 24-week trial and looking at the data at 6 weeks, that needs to be done with caution. But I think holistic -- generally, you look at this information carefully, and you'd say it's largely consistent with the 6-week data for teprotumumab.
>
> ***On the safety side, importantly, there were no serious adverse events.*** We actually saw no headaches in this trial either. And again, this is from a tolerability standpoint, we had the subcutaneous injection, which was very well tolerated in this trial as it had been in the Phase I trial.
>
> Finally, we have an ongoing study in thyroid eye disease that's much bigger than the proof of concept, and this is our ASCEND GO-2 trial. It's a pivotal design IIb trial, testing 3 different dosage arms with an emphasis on the 2 higher doses and comparing all those to placebo.
>
> * * *
>
> ***And then from a safety and tolerability standpoint, similar to our thyroid eye disease trial, a nice profile. Again, early days, but we're looking good from a safety and tolerability standpoint.***
>
> * * *
>
> The first point around registration, that's a pretty well-trodden path, I think, right now, given the nice data we saw from argenx and their trial design and not just the argenx Phase III, but some other mechanisms that are maybe not quite as attractive from a patient standpoint, but have completed Phase III trials. I think we know what the FDA is expecting from a primary efficacy analysis standpoint, which would be a big part of the registration.

(Emphasis added).

250. The statements referenced above in ¶249 were materially false and misleading when made for the reasons set forth in ¶171 above. The statements about "no serious adverse events," "safety" and "tolerability" were materially false and misleading because there was an anticipated risk of substantially elevated cholesterol levels and Immunovant failed to test for cholesterol.

251. On November 12, 2020, Immunovant filed its quarterly report on Form 10-Q with the SEC for 2Q20 (the "2Q20 Form 10-Q"), which was signed by Defendants Salzmann and Connealy. The 2Q20 Form 10-Q discussed Immunovant, the trials for IMVT-1401, and the efficacy and safety of IMVT-1401 as referenced in ¶203 above. The 2Q20 Form 10-Q were materially false and misleading when made for the reasons set forth in ¶204.

252. On January 12, 2021, Immunovant issued a press release titled "Immunovant Appoints Rita Jain Chief Medical Officer and Provides Corporate Update" (the "1/12/21 Press Release"), which it filed with the SEC on Form 8-K. The 1/12/21 Press Release quoted Defendant Salzmann who stated, in pertinent part, as follows:

> We're extremely excited about the potential for IMVT-1401 in multiple therapeutic areas and have ***made good progress toward the initiation of our Phase 3 trial of IMVT-1401 in Myasthenia Gravis (MG), which remains on track for the first half of 2021[.]*** I'm also pleased with the team's progress ***developing INDs for new indications. We remain on track to announce three new indications by August of 2021***[.]

253. The statements referenced above in ¶252 were materially false and misleading when made for the reasons set forth in ¶171. Additionally, Defendant Salzmann's statements that the Company has "made good progress toward the initiation of our Phase 3 trial of IMVT-140" and that "[w]e remain on track to announce three new indications by August of 2021" because by this time the Company was in the process of performing an internal investigation about the increases in cholesterol from the ASCEND GO-2 Phase 2b trial. Defendants knew, or recklessly disregarded, that the high cholesterol levels recorded in the ASCEND GO-2 Phase 2b trial would slow down the Company's timetable for the initiation of its Phase 3 trial and the development of INDs for three new indications.

Immunovant's Class Period SEC Filings Omitted Known Trends, Events and Uncertainties that Were Impacting, and Would Impact, the Company's Financial Results

254. Pursuant to Item 7 of Form 10-K and Item 2 of Form 10-Q, Immunovant's Class Period SEC filings were required to furnish the information required under Item 303 of Regulation S-K [17 C.F.R. §229.303], including any known trends, events or uncertainties that have caused or are reasonably likely to cause the registrant's financial information not to be indicative of future operating results.

255. The known trends, events, or uncertainties referenced in ¶116 above were having, and were reasonably likely to have, an impact on the Company's continuing operations and, therefore, were required to be disclosed by Defendants pursuant to Item 303 in the 1/17/20 Registration Statement, the 3Q19 Form 10-Q, the 4/10/20 Registration Statement, the 4/14/20 Prospectus, the 2020 Form 10-K, the September 2020 Offering Documents, and the 2Q20 Form 10-Q but were not.

Immunovant's Class Period SEC Filings Omitted to Include Significant Risk Factors Required to Be Disclosed Therein

256. Pursuant to Item 1A of Form 10-K, Immunovant's 2020 Form 10-K was required to furnish the information pursuant to Item 503 of Regulation S-K [17 C.F.R. §229.303], including, among other things, a "discussion of the most significant factors that make the offering risky or speculative." Pursuant to Item 1A of Form 10-Q, Immunovant's Class Period Forms 10-Q were required to "[s]et forth any material changes from risk factors as previously disclosed" in Immunovant's 2020 Form 10-K pursuant to Item 503 of Regulation S-K [17 C.F.R. §229.503]. Defendants failed to comply with Item 503 by failing to disclose risk factors or material changes in risk factors in these SEC filings.

257. Specifically, Defendants failed to disclose the risk factors set forth in ¶119 above in Immunovant's 1/17/20 Registration Statement, the 3Q19 Form 10-Q, the 4/10/20 Registration

Statement, the 4/14/20 Prospectus, the 2020 Form 10-K, the September 2020 Offering Documents, and the 2Q20 Form 10-Q as required under Item 503.

258. Additionally, any purported risk warnings or cautionary language provided by Defendants during the Class Period, including the language referenced in ¶¶121, 123, 125, and 127 above, did not adequately warn investors about the materially false and misleading statements alleged herein. These risk warnings: (i) were false or misleading as a matter of current or historical fact; and/or (ii) were not meaningful because, among other things, they were vague, boilerplate and did not adequately warn of the true risks of investing in Immunovant.

ADDITIONAL SCIENTER ALLEGATIONS

259. As alleged herein, the Defendants acted with scienter in that Defendants knew, or recklessly disregarded, that the public documents and statements issued or disseminated in the name of the Company (or in their own name) were materially false and misleading; knew or recklessly disregarded, that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. Defendants, by virtue of their receipt of information reflecting the true facts regarding Immunovant and IMVT-1401, their control over, and/or receipt and/or modification of Immunovant's allegedly materially misleading misstatements, were active and culpable participants in the fraudulent scheme alleged herein.

260. Defendants knew and/or recklessly disregarded the falsity and misleading nature of the information which they caused to be disseminated to the investing public. The ongoing fraudulent scheme described herein could not have been perpetrated during the Class Period without the knowledge and complicity or, at least, the reckless disregard of the personnel at the highest levels of the Company, including the Exchange Act Individual Defendants.

261. Defendant Salzmann was a highly experienced and knowledgeable professional in the biopharmaceutical industry and had extensive experience with clinical trials of drugs. Indeed, prior to his employment at the Company, he served as Global Brand Development Leader in Immunology at Eli Lilly, where he designed and executed a comprehensive indication development strategy and oversaw Phase 2 and 3 clinical trial execution (from November 2018 to June 2019). From March 2013 to October 2018, Defendant Salzmann was Head of U.S. Immunology at Eli Lilly, and Managing Director of Lilly Alps from January 2011 to April 2013. From January 2008 to December 2010, Defendant Salzmann was the Head of Marketing for Eli Lilly China. Defendant Salzmann also served during the Class Period as a member of the board of directors of Corbus Pharmaceuticals Holdings, Inc., a publicly traded biotechnology company. Defendant Salzmann would have been aware of the science and the scientific literature related to serum albumin, thyroid levels, and other issues that made elevated LDL and cholesterol levels an anticipated risk of IMVT-1401. Defendant Salzmann would also have been aware that according to good clinical practices and standards, Immunovant should have designed each of its phase 1 and 2 trials to test for and report on cholesterol levels due to the anticipated risk of elevated cholesterol based on the science, the scientific literature, and Immunovant's animal study results showing a substantial increase in cholesterol for animals which received IMVT-1401.

262. Defendants Salzmann and Connealy were executive officers of Immunovant, and at a minimum, should have been aware of key facts related to the testing and risks involved with IMVT-1401, including that the animal studies showed an increase in cholesterol, that an increase in cholesterol levels was an anticipated risk of IMVT-1401, and that the completed clinical trials of IMVT-1401 had not tested for cholesterol and that the ASCEND GO-2 Phase 2b trial was the first time the Company tested for cholesterol in clinical trials.

263. Defendant Salzmann, as the CEO of the Company and with his scientific background, would have been directly involved with the design, approval and/or review of the IMVT-1401 clinical trials as well as the preparation and/or review of all reports and studies that were provide to the FDA concerning IMVT-1401, including the animal studies showing an increase in cholesterol and information concerning the design of the clinical trials, including the lack of cholesterol testing.

264. Defendant Connealy would have been involved with the financial aspects of the trials, including the expected timetable for the trials and the total costs of the trials, and anticipated FDA approval, such that Defendant Connealy could plan the financial needs of the Company. Defendant Connealy would have been aware of the anticipated risk of rising cholesterol levels in order to properly plan for delays and contingencies in the event the ASCEND GO-2 Phase 2b trial revealed that IMVT-1401 increased cholesterol levels.

265. Defendant Wong would also have been aware of the fraud alleged herein. Defendant Wong was an investor in Legacy Immunovant, was the CEO and primary investor through affiliated entities in HSAC, and was directly involved with the process which resulted in HSAC's acquisition of Legacy Immunovant. As alleged above, HSAC and Defendant Wong engaged in talks for approximately one year about HSAC acquiring Legacy Immunovant and Wong, through HSAC, engaged in formal due diligence at least from May 11, 2019, to September 29, 2019. Through this due diligence, Defendant Wong would have known, or was reckless in not knowing, that increased cholesterol levels were an anticipated risk of IMVT-1401, that the clinical trials for IMVT-1401 prior to the ASCEND GO-2 Phase 2b trial failed to test for cholesterol, and that the animal studies for IMVT-1401 revealed substantially increased cholesterol levels in test animals. Additionally, Defendant Wong remained a beneficial owner of a large amount of Immunovant securities and had the right to obtain additional shares of Immunovant after the merger.

266. Furthermore, the fraud alleged herein related to testing and development of IMVT-1401, which was the core and sole business of Immunovant, so knowledge of the fraud may be imputed to Defendants. Immunovant was a small company with only approximately 19 employees during 2019 and 42 employees during 2020. Since Immunovant had no other drugs or products other than IMVT-1401, and since IMVT-1401 was in ongoing clinical trials during the Class Period, knowledge of the fraud may be imputed to Defendants.

267. Likewise, the Exchange Act Individual Defendants, by virtue of their high-level positions with the Company or HSAC, directly participated in the management of the Company or HSAC, were directly involved in the day-to-day operations of the Company or HSAC at the highest levels and were privy to confidential proprietary information concerning the Company or HSAC and IMVT-1401, as alleged herein. The Exchange Act Individual Defendants had the ultimate authority over and were involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein, were aware, or recklessly disregarded, that the false and misleading statements regarding the Company were being issued, and approved or ratified these statements, in violation of the federal securities laws.

268. In addition, Defendants also possessed knowledge of facts or had access to information contradicting their public statements. Defendants failed to review or check information that they had a duty to monitor or ignored obvious signs of fraud. Defendants knew, or had access to, among other things, the IMVT-1401 animal studies, scientific information showing that elevated cholesterol levels were an anticipated risk of IMVT-1401, and details about the design of the clinical trials, including that Immunovant had not tested for cholesterol during the Phase 1 trials or any Phase 2 trials completed prior to the ASCEND GO-2 Phase 2b trial. Accordingly, Defendants were in possession of, or had access to, facts indicating that Defendants' statements about the safety of

IMVT-1401 were materially false and misleading, and that there was a substantial risk that there would be a delay in the timetable for viability of IMVT-1401 due to issues with cholesterol.

269. Defendants' materially false and misleading statements and material omissions caused Immunovant securities to be artificially inflated.

270. Additionally, Defendants possessed substantial motives for misrepresenting the safety and viability of IMVT-1401 throughout the Class Period.

271. Defendant Wong had a substantial financial motives for engaging in the fraud alleged herein. Defendant Wong, through entities under his control, founded the blank-check company HSAC. He, therefore, had a financial motive to ensure that HSAC acquired a company within two years so he would not need to return the capital raised from investors. Defendant Wong also had a financial motive for HSAC to acquire Legacy Immunovant because Defendant Wong had owned shares in Legacy Immunovant since before HSAC's IPO.

272. Similarly, Defendant Roivant, as the controlling shareholder of Legacy Immunovant, was financially motivated to engage in the fraud alleged herein in order to monetize its investment in IMVT-1401 and Immunovant by selling Legacy Immunovant to HSAC.

273. Furthermore, the structure of the Share Exchange Agreement in connection with HSAC's acquisition of Legacy Immunovant provided strong financial motivation for Defendants Roivant, Immunovant, and Wong to engage in the fraud alleged herein. Under the terms of that agreement, the "Sellers" of Legacy Immunovant, including Roivant and Defendant Wong, were entitled to receive up to 20 million "earnout shares" of Immunovant common stock if the stock price exceeded pre-defined targets. The earnout shares provision states, in pertinent part, as follows:

> ***Earnout Shares***
>
> The Sellers are entitled to receive up to an additional 20,000,000 shares of the Company's common stock (the "Earnout Shares") if the volume-weighted average price of the Company's shares equals or exceeds the following prices for any 20

> trading days within any 30 trading-day period (the "Trading Period") following December 18, 2019, the date of the closing of the Business Combination:
>
> (i) during any Trading Period prior to March 31, 2023, 10,000,000 Earnout Shares upon the achievement of a volume-weighted average price of at least $17.50 per share; and
>
> (ii) during any Trading Period prior to March 31, 2025, 10,000,000 Earnout Shares upon the achievement of a volume-weighted average price of at least $31.50 per share (each of (i) and (ii) are a "Milestone").

274. At the time the merger was approved, Immunovant common stock traded at $11.49 per share, it exceeded $17.50 per share on May 12, 2020, and exceeded $31.50 on September 17, 2020. Therefore, those that were entitled to the earnout shares were in position to financially benefit from the artificial inflation of the price of Immunovant common stock. The artificial inflation in the price of Immunovant common stock enabled Defendants Roivant and Wong to qualify for and receive the earnout shares during the Class Period.

275. Additionally, the artificial inflation of the price of Immunovant common stock enabled Immunovant and various selling shareholders, including entities controlled and owned by Defendant Wong, to sell hundreds of millions of dollars of Immunovant common stock to investors through several public follow-on offerings and shelf registrations, including on or about April 10, 2020, April 14, 2020, and September 2, 2020. In fact, on or about January 15, 2021, approximately two weeks before Immunovant announced the halting of its IMVT-1401 trials on February 2, 2021, Immunovant filed a registration statement for a shelf offering for $150 million worth of common stock and selling stockholders, including entities controlled by Defendant Wong, filed a prospectus for the sale of nearly one million shares of Immunovant common stock. The timing of these stock registrations as so close to the announcement of the halting of the Immunovant's phase 2 studies supports scienter.

276. Below is a chart which summarizes some of Defendants' financial motivations to engage in the fraud alleged herein:

Date	Deal / Event	Who Benefitted and By How Much	IMVT (HSAC) Stock Price
05/10/2019	HSAC IPO: Raised $115 million from public investors	• $115 million raised from public investors • Roderick Wong (CEO of HSAC) • Funds from IPO must be returned if HSAC does not make acquisition within 24 months	$10.00 per unit
09/29/2019	HSAC acquisition of Legacy Immunovant Announced	• Roivant controlling Legacy Immunovant shareholder • Roderick Wong beneficially owns 2,604,166 of Legacy Immunovant shares or 3% of Legacy Immunovant	$10.02 per share
12/16/2019	HSAC acquisition of Legacy Immunovant Approved	• Transaction valued at $421,802,770 • Selling shareholders include Roivant; Roderick Wong entities RTW Master Fund and RTW Innovation Fund; and HanAll Biopharma Co., Ltd. • Selling shareholders entitled to up to 10 million shares if IMVT exceeds $17.50 • Selling shareholders entitled to up to 10 million shares if IMVT exceeds $31.50	$11.49 per share
04/09/2020	Registered shelf public offering by selling shareholders listed in the next column	• RTW Master Fund, Ltd.: owned 3,235,952 shares and registered 100% • RTW Innovation Master Fund, Ltd.: owned 1,037,580 shares and registered 100% • RTW Venture Fund Limited: owned 152,574 and registered 100% • Health Sciences Holdings, LLC (Sponsor): owned 2,875,000 and registered 100% • HanAll BioPharma Co., Ltd.	$15.54 per share
04/14/2020	Immunovant follow-on offering	Immunovant raised $139.4 million from public investors	$14.50 per share
09/02/2020-09/04/2020	Immunovant follow-on offering	Immunovant raised $200 million from investors	$33.00 per share

Date	Deal / Event	Who Benefitted and By How Much	IMVT (HSAC) Stock Price
01/15/2021	Registered shelf public offering of nearly 1 million shares of Immunovant common stock by selling shareholders listed in the next column	• RTW Master Fund, Ltd.: registered 662,912 for sale • RTW Innovation Master Fund, Ltd.: registered 174,241 for sale • HanAll Biopharma Co., Ltd. • The shares registered for sale consist of additional shares issued to each stockholder in September 2020 upon the achievement of the second earnout milestone	$44.15 per share
01/15/2021	Immunovant filed registration statement for shelf offering of common stock	Registered for sale of up to $150 million in Immunovant common stock to public investors	$44.15 per share

277. Taken collectively, the facts alleged above demonstrate a strong inference that Defendants acted with scienter.

LOSS CAUSATION/ECONOMIC LOSS

278. During the Class Period, as detailed herein, Defendants engaged in a scheme to deceive the market and a course of conduct which artificially inflated the prices of Immunovant common stock and operated as a fraud or deceit on Class Period purchasers of Immunovant securities. When Defendants' prior misrepresentations and fraudulent conduct were disclosed and became apparent to the market, the price of Immunovant common stock fell precipitously as the prior artificial inflation came out. As a result of their purchases of Immunovant common stock during the Class Period, Plaintiff and the other Class members suffered economic loss, *i.e.*, damages, under the federal securities laws.

279. Defendants' false and misleading statements, which as alleged above were made without any reasonable basis, had the intended effect and caused Immunovant common stock to trade at artificially inflated levels throughout the Class Period.

280. On February 2, 2021, Immunovant announced the voluntary pause in clinical dosing of IMVT-1401 as a result of patients experiencing an increase in LDL and cholesterol levels, as set

forth in ¶¶129-133 above. In response to the Company's announcement on February 2, 2021, shares of the Company's stock fell $18.22 per share, or 42.08%, from a close of $43.30 per share before the announcement, to close at $25.08 per share, on extremely heavy trading volume of 11.76 million shares.

281. Then, on June 1, 2021, the Company announced additional details about the connection between IMVT-1401 and cholesterol, including, among other things, that the observed increases in LDL and cholesterol appeared to be caused by a reduction in albumin levels and relate to all indications of IMVT-1401. In response to the Company's announcements on June 1, 2021, shares of the Company's stock fell from $5.76 per share, or 38%, from a close of $15.16 per share before the announcement, to close at $9.40 per share, on extremely heavy trading volume of 16.92 million shares.

282. The declines in the price of Immunovant common stock after the disclosures came to light was a direct result of the nature and extent of Defendants' fraud finally being revealed to investors and the market. The timing and magnitude of the price declines in Immunovant common stock negates any inference that the loss suffered by Plaintiff and the other Class members were caused by changed market conditions, macroeconomic or industry factors or Company-specific facts unrelated to Defendants' fraudulent conduct. The economic loss, *i.e.*, damages, suffered by Plaintiff and the other Class members was a direct result of Defendants' fraudulent scheme to artificially inflate the price of Immunovant securities and the subsequent significant declines in the value of Immunovant securities when Defendants' prior misrepresentations and other fraudulent conduct were revealed.

APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD ON THE MARKET DOCTRINE

283. At all relevant times, the market for Immunovant common stock was an efficient market for the following reasons, among others:

(a) Immunovant common stock met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) as a regulated issuer, Immunovant filed periodic public reports with the SEC and the NASDAQ;

(c) Immunovant regularly communicated with public investors via established market communication mechanisms, including regular disseminations of press releases on the national circuits of major newswire services and other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(d) Immunovant was followed by several securities analysts employed by major brokerage firms who wrote reports which were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

284. As a result of the foregoing, the market for Immunovant securities promptly digested current information regarding Immunovant from all publicly available sources and reflected such information in the prices of the securities. Under these circumstances, all purchasers of Immunovant securities during the Class Period suffered similar injury through their purchase(s) of Immunovant securities at artificially inflated prices and a presumption of reliance applies.

APPLICABILITY OF PRESUMPTION OF RELIANCE: AFFILIATED UTE DOCTRINE

285. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. U.S.*, 406 U.S. 128 (1972), because

Defendants' material omissions during the Class Period caused harm to Plaintiff and the Class. Because the Complaint alleges Defendants' failure to disclose material adverse information regarding Immunovant and the testing, safety and prospects of IMVT-1401 - information that Defendants were obligated to disclose - positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions.

286. Given the importance of the Class Period material omissions set forth above, that requirement is satisfied here, and, therefore, *Affiliated Ute* provides a separate, distinct basis for finding the applicability of a presumption of reliance.

NO SAFE HARBOR

287. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. Many of the specific statements pleaded herein were not identified as "forward-looking statements" when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements were made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of the company making the statement who knew that those statements were false or misleading when made.

COUNT IV

Violations of Section 10(b) of the Exchange Act and Rules 10b-5(a), (b), and (c) Promulgated Thereunder Against Immunovant, Roivant and the Exchange Act Individual Defendants

288. Plaintiff repeats and realleges each and every allegation contained above in ¶¶1-145, 167-287 as if fully set forth herein.

289. This Count is asserted against Immunovant, Roivant and the Exchange Act Individual Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. §78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

290. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Immunovant securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Immunovant securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

291. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the

market for Immunovant securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Immunovant's finances and business prospects.

292. By virtue of their positions at Immunovant and/or HSAC, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

293. Defendant Wong participated in the business combination process including the conducting of a due diligence investigation into Immunovant. Defendant Wong was HSAC's CEO prior to its acquisition of Immunovant and is substantially intertwined in Immunovant's business, studies, and IMVT-1401 drug candidate through the RTW Entities. Defendant Wong, through the RTW Entities, owned approximately 3% of the shares of Legacy Immunovant. By virtue of his involvement with Immunovant, Defendant Wong had actual knowledge of the materially false and misleading statements and omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendant Wong acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants.

294. Immunovant began as a division of Roivant. Defendant Roivant was a controlling shareholder of Legacy Immunovant and Immunovant at all times relevant herein. Defendant Roivant was the majority selling shareholder in the sale of Legacy Immunovant to HSAC, and remained a controlling shareholder after the sale. Roivant was intimately involved with IMVT-1401, including the licensing of IMVT-1401 from HanAll, and, acted knowingly or with reckless disregard for the truth.

295. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Immunovant and/or HSAC, the Exchange Act Individual Defendants had knowledge of the details of Immunovant's internal affairs.

296. The Exchange Act Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Exchange Act Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Immunovant. As officers and/or directors of Immunovant and/or HSAC, the Exchange Act Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Immunovant's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Immunovant securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning IMVT-1401 and Immunovant which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Immunovant securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants and were damaged thereby.

297. During the Class Period, Immunovant securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Immunovant securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Immunovant securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Immunovant securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

298. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

299. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT V

Violations of Section 20(a) of the Exchange Act Against the Exchange Act Individual Defendants and Roivant

300. Plaintiff repeats and realleges each and every allegation contained above in ¶¶1-145, 167-299 as if fully set forth herein.

301. Defendants Salzmann, Connealy and Roivant were controlling persons of Immunovant and Defendant Wong was a controlling person of HSAC.

302. During the Class Period, the Individual Defendants participated in the operation and management of Immunovant or HSAC, and conducted and participated, directly and indirectly, in the conduct of Immunovant's or HSAC'a business affairs. Because of their senior positions, they knew the adverse non-public information about Immunovant's business and IMVT-1401.

303. As officers and/or directors of Immunovant or HSAC, the Exchange Act Individual Defendants had a duty to disseminate accurate and truthful information with respect to IMVT-1401 and Immunovant's business and prospects, and to correct promptly any public statements issued by Immunovant which had become materially false or misleading.

304. Because of their positions of control and authority as senior officers at Immunovant or HSAC, the Exchange Act Individual Defendants, were able to, and did, control the contents of the various reports, press releases and public filings which Immunovant or HSAC disseminated in the marketplace during the Class Period concerning Immunovant and IMVT-1401. Throughout the Class Period, the Exchange Act Individual Defendants exercised their power and authority to cause Immunovant to engage in the wrongful acts complained of herein. The Exchange Act Individual Defendants, therefore, were "controlling persons" of Immunovant within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Immunovant securities.

305. Each of the Exchange Act Individual Defendants, therefore, acted as a controlling person of Immunovant. By reason of their senior management positions and/or being directors of Immunovant or HSAC, each of the Exchange Act Individual Defendants had the power to direct the actions of, and exercised the same to cause, Immunovant to engage in the unlawful acts and conduct

complained of herein. Each of the Exchange Act Individual Defendants exercised control over the general operations of Immunovant and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

306. Furthermore, Defendant Roivant was a control person of Legacy Immunovant and Immunovant at all relevant times herein. Immunovant began as a division of Roivant and Roivant owned more than a majority of Immunovant stock during the Class Period and had, and exercised control over, Immunovant.

307. By reason of the above conduct, the Exchange Act Individual Defendants and Roivant are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Immunovant.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Declaring this action to be a class action properly maintained pursuant to Rule 23(a) and (b)(3) of the Federal Rules of Civil Procedure;

B. Awarding Plaintiff and other members of the Class damages together with interest thereon;

C. With respect to Count II, ordering that the September 2020 Offering be rescinded;

D. Awarding Plaintiff and other members of the Class their costs and expenses of this litigation, including reasonable attorneys' fees, accountants' fees and experts' fees and other costs and disbursements; and

E. Awarding Plaintiff and other members of the Class such other and further relief as may be just and proper under the circumstances.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

DATED: March 15, 2022

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Lead Counsel for Lead Plaintiff

CERTIFICATE OF SERVICE

I, Evan J. Kaufman, hereby certify that on March 15, 2022, I authorized a true and correct copy of the foregoing document to be electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such public filing to all counsel registered to receive such notice.

/s/ Evan J. Kaufman
EVAN J. KAUFMAN